



**DEPARTMENT OF DEFENSE  
FREEDOM OF INFORMATION DIVISION  
1155 DEFENSE PENTAGON  
WASHINGTON, DC 20301-1155**

Ref: 20-F-1410  
October 23 2020

Russ Kick  
New England Anti-Vivisection Society  
333 Washington Street, Suite 850  
Boston, MA 02108

Dear Mr. Kick:

This is a final response to your July 27, 2020 Freedom of Information Act (FOIA) request, a copy of which is enclosed for your convenience. We received your request on July 28, 2020, and assigned it case number 20-F-1410. We ask that you use this number when referring to your request.

The Uniformed Services University of Health Sciences, a component of the Office of the Secretary of Defense, conducted a search of their records systems and located 235 pages determined to be responsive to your request. Mr. Keith Van Nostrand, Program Administrative Specialist, in his capacity as an Initial Denial Authority (IDA), has determined that portions of the 235 responsive pages are exempt from release pursuant to FOIA, 5 U.S.C. § 552. The redacted information is withheld in accordance with 5 U.S.C. § 552 (b)(2), protects records related solely to the internal personnel rules and practices of an agency; 5 U.S.C. § 552 (b)(4), which applies to confidential information submitted to the government by a person and for which disclosure may reasonably be expected to impair the legitimate commercial, financial, business, or research interests of that person; 5 U.S.C. § 552 (b)(5), which pertains to inter- and intra-agency information of a pre-decisional, deliberative nature which, if released, could reasonably be expected to interfere with the government's deliberative process; and 5 U.S.C. § 552 (b)(6), as disclosure of the information would constitute a clearly unwarranted invasion of the personal privacy of individuals.

In this instance, fees for processing your request were below the threshold for requiring payment. Please note that fees may be assessed on future request.

If you have any questions or concerns about the foregoing or about the processing of your request, please do not hesitate to contact your Action Officer, Matthew Koch, at 571-372-0412 or [Matthew.j.koch24.civ@mail.mil](mailto:Matthew.j.koch24.civ@mail.mil). Additionally, if you have concerns about service received by our office, please contact a member of our Leadership Team at 571-372-0498 or Toll Free at 866-574-4970.

Should you wish to inquire about mediation services, you may contact the OSD/JS FOIA Public Liaison, Tonya R. Fuentes, at 571-372-0462 or by email at [OSD.FOIALiaison@mail.mil](mailto:OSD.FOIALiaison@mail.mil), or the Office of Government Information Services (OGIS) at the National Archives and Records Administration. The contact information for OGIS is as follows:

Office of Government Information Services  
National Archives and Records Administration  
8601 Adelphi Road-OGIS  
College Park, MD 20740  
E-mail: [ogis@nara.gov](mailto:ogis@nara.gov)  
Telephone: 202-741-5770  
Fax: 202-741-5769  
Toll-free: 1-877-684-6448

You have the right to appeal to the appellate authority, Ms. Joo Chung, Director of Oversight and Compliance, Office of the Secretary of Defense, by writing directly to OCMO Office of the Chief Management Officer, 4800 Mark Center Drive, ATTN: DPCLTD, FOIA Appeals, Mailbox# 24, Alexandria, VA 22350-1700.

Your appeal must be postmarked within 90 calendar days of the date of this response. Alternatively, you may email your appeal to [osd.foia-appeal@mail.mil](mailto:osd.foia-appeal@mail.mil). If you use email, please include the words "FOIA Appeal" in the subject of the email. Please also reference case number 20-F-1410 in any appeal correspondence.

We appreciate your patience in the processing of your request. As stated previously, please contact your Action Officer, Matthew Koch, and reference FOIA case number 20-F-1410 if you have any questions or concerns.

Sincerely,

*for Pamela Andrews*  
Stephanie L. Carr  
Chief

Enclosures:  
As stated

## Appendix 3: Line Drawings

Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5" x 11" or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.







**GROUND FLOOR**  
**NORTH EAST CORNER**

1/18/13





## 10/01/14

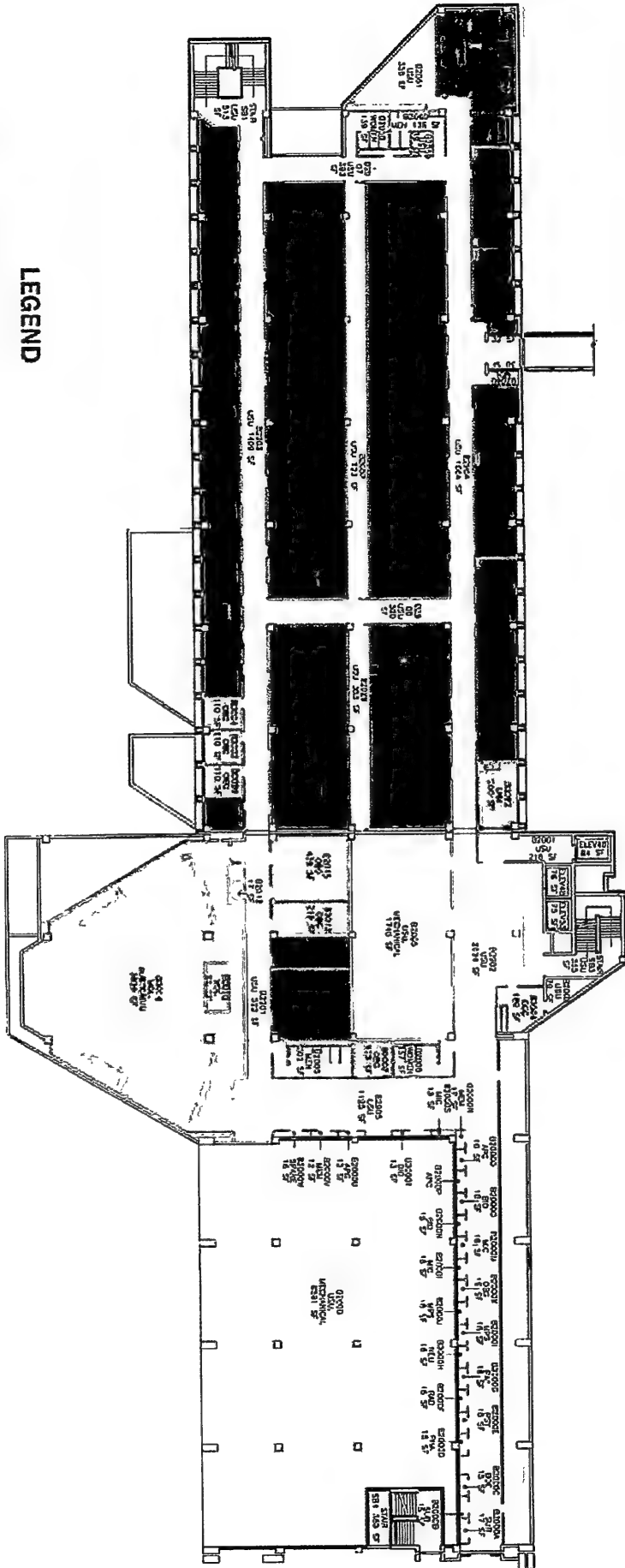




## 5/21/15

- ☒ ANATOMY, PHYSIOLOGY AND GENETICS
- ☒ DERMATOLOGY
- ☒ LABORATORY ANIMAL MEDICINE
- ☒ MULTIDISCIPLINE LABORATORIES
- ☒ GRADUATE EDUCATION OFFICE
- ☒ PHARMACOLOGY
- ☐ UNIFORMED SERVICES UNIVERSITY



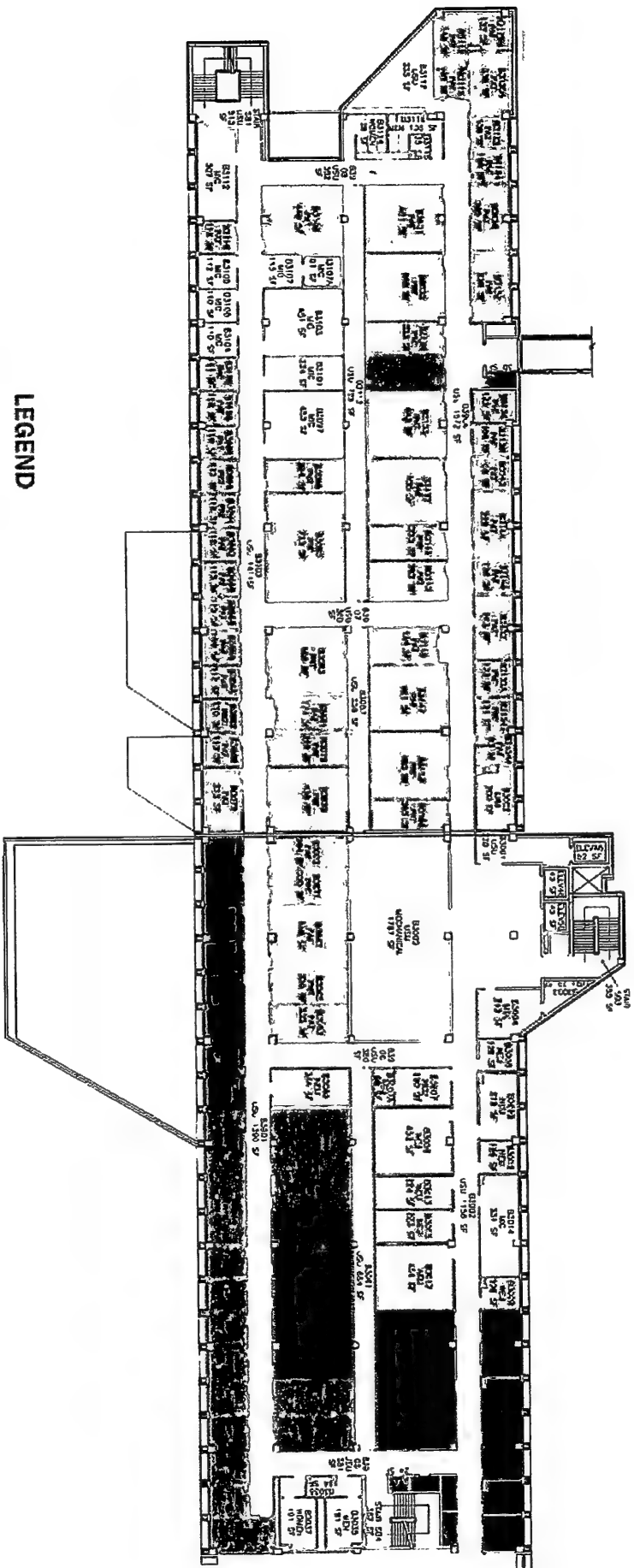


# LEGEND

- ANATOMY, PHYSIOLOGY AND GENETICS
- BIOLOGICAL INSTRUMENTATION CENTER
- LABORATORY ANIMAL MEDICINE
- MILITARY AND EMERGENCY MEDICINE
- MULTIDISCIPLINARY LABORATORIES
- OBSTETRICS/GYNECOLOGY
- UNIFORMED SERVICES UNIVERSITY
- OFFICE OF GENERAL COUNSEL







# LEGEND

■ BIOCHEMISTRY  
 ■ BIOLOGICAL INSTRUMENTATION  
 ■ CENTER  
 ■ ENVIRONMENTAL, HEALTH AND OCCUPATIONAL SAFETY

□ LABORATORY: ANIMAL  
 □ MEDICINE  
 □ MEDICAL & CLINICAL  
 □ PSYCHOLOGY  
 □ MICROBIOLOGY  
 □ MULTIDISCIPLINE LABORATORIES

□ NEUROLOGY  
 □ PATHOLOGY  
 □ PSYCHIATRY  
 □ UNIFORMED SERVICES

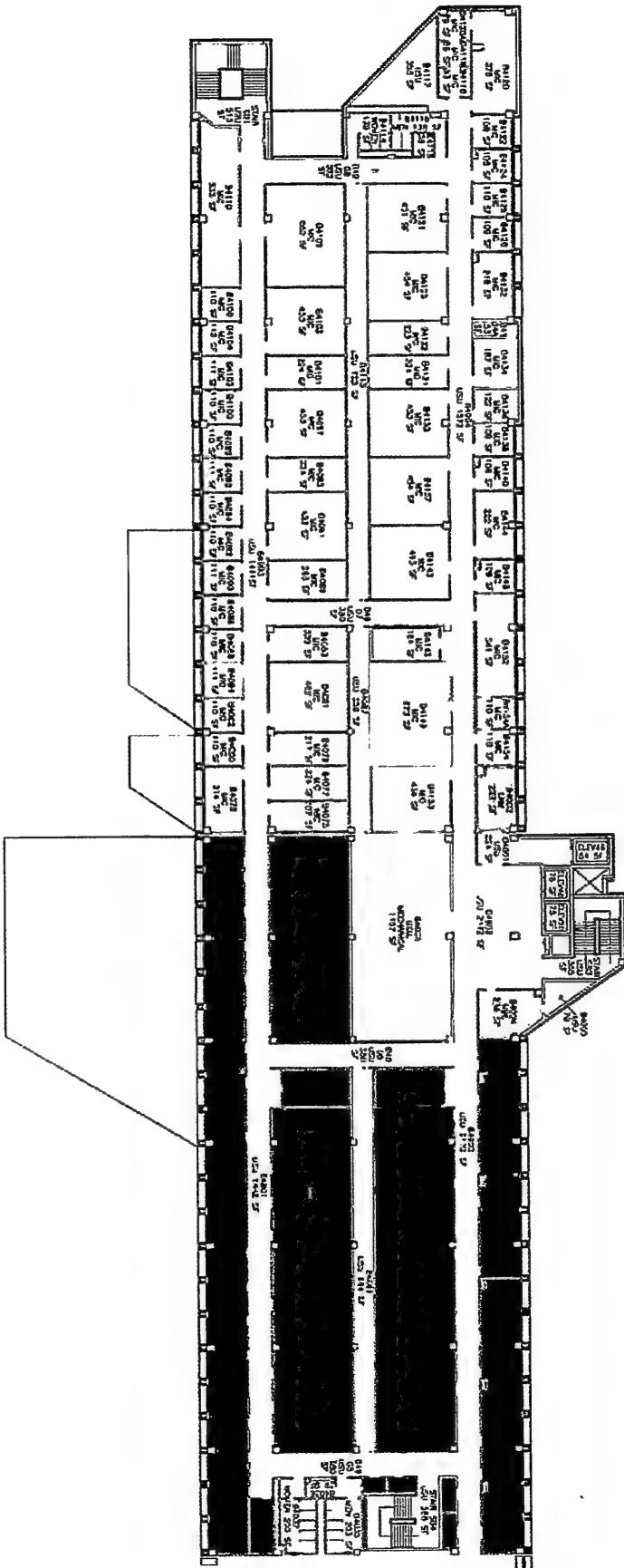
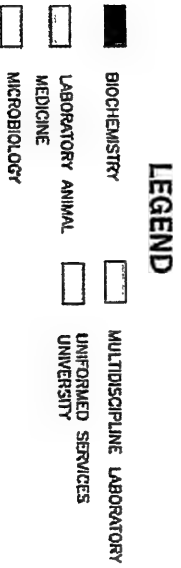


## B BUILDING THIRD FLOOR PLAN

1/16/13



5/21/2015





## Appendix 8: IACUC/OB Minutes

Please provide the latest two minutes of the IACUC/OB meetings.

134

8/16





UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD  
BETHESDA, MARYLAND 20814-4799



Institutional Animal Care and Use Committee

(b)(6)

December 15, 2016

MEMORANDUM FOR RECORD

SUBJECT: Minutes of the Institutional Animal Care and Use Committee of the Uniformed Services University of the Health Sciences Meeting (b)(2)

I. Under the provisions of USUHS Instruction 3204, a meeting of the Institutional Animal Care and Use Committee (IACUC) was held on December 15, 2016, in (b)(2). The purpose of the meeting was to review animal care and welfare issues. A memorandum detailing the meeting agenda was distributed on December 8, 2016. Dr. (b)(6) Vice Chair, called the meeting to order at 1306.

II. Attendance:

A. Voting members present:

\* Member Numbers: 1, 4, 9, 15, 17, 19, 21, 30, 32

Note: A waiver was obtained from ACURO to conduct the meeting without an unaffiliated member present.

B. Voting member(s) absent:

\* Member Numbers: 2, 3, 8, 11, 13, 16, 23, 25, 30

C. Non-Voting members present:

\* Member Number: 5

D. IACUC staff member(s) present:

\* Member Numbers: 33, 38, 41

E. Guests:

\* Assistant Vice President for Research Initiatives and Compliance

\* Principal Investigator (PI) for protocol (b)(2)

\* PI for protocol (b)(2)

III. Full Committee Review(s):

A. The Review of (b)(2) Triennial:

The objectives and procedures proposed in the initial protocol (b)(2) were summarized by the PI. (b)(2)

(b)(2), (b)(5)

he committee voted unanimously (9-0-0) that modifications were required to secure approval and modification approval could be completed by Designated Member Review (DMR). The Chair appointed a member of the IACUC to complete the review of this protocol.

B. The Review of (b)(2) Major Modification:

The objectives and procedures proposed in the major modification request for protocol (b)(2) were summarized by the PI. After addressing questions from the committee members, the PI left the meeting. The committee voted unanimously (9-0-0) that modifications were required to secure approval and modification approval could be completed by DMR. The Chair appointed a member of the IACUC to complete the review of this protocol.

IV. Minutes.

- A. The November 16, 2016, IACUC meeting minutes were approved by unanimous voice vote of the committee (9-0-0).

V. Old Business.

A. Review of Animal Study Protocols.

1. These protocols received significant, detailed review by the IACUC prior to the meeting. A motion for approval of the protocols listed below was made, seconded, and passed by voice vote:

None.

2. The following animal study protocols were approved via DMR before the meeting:

(b)(2)	(Major Mod)	Investigation of Traumatic Brain Injury in the Ferret Using Advanced MRI and Histopathology Techniques
	(Closing)	Establishment and/or Maintenance of a Mice Breeding Colony for Analysis to Tolerance in EAE
	(Closing)	Induction of Tolerance to Factor FVIII in Hemophilic Mice
	(1 <sup>st</sup> Annual)	Effect of Home Cage Bedding in the Induction Chamber on Serum Cortisol Levels in Response to Isoflurane-Induced Anesthesia in Mice
	(Closing)	USUHS Center for LAM Animal Holding Protocol (Multiple Species)
	(Triennial)	USUHS Center for LAM Animal Holding Protocol (Multiple Species)



(b)(2)

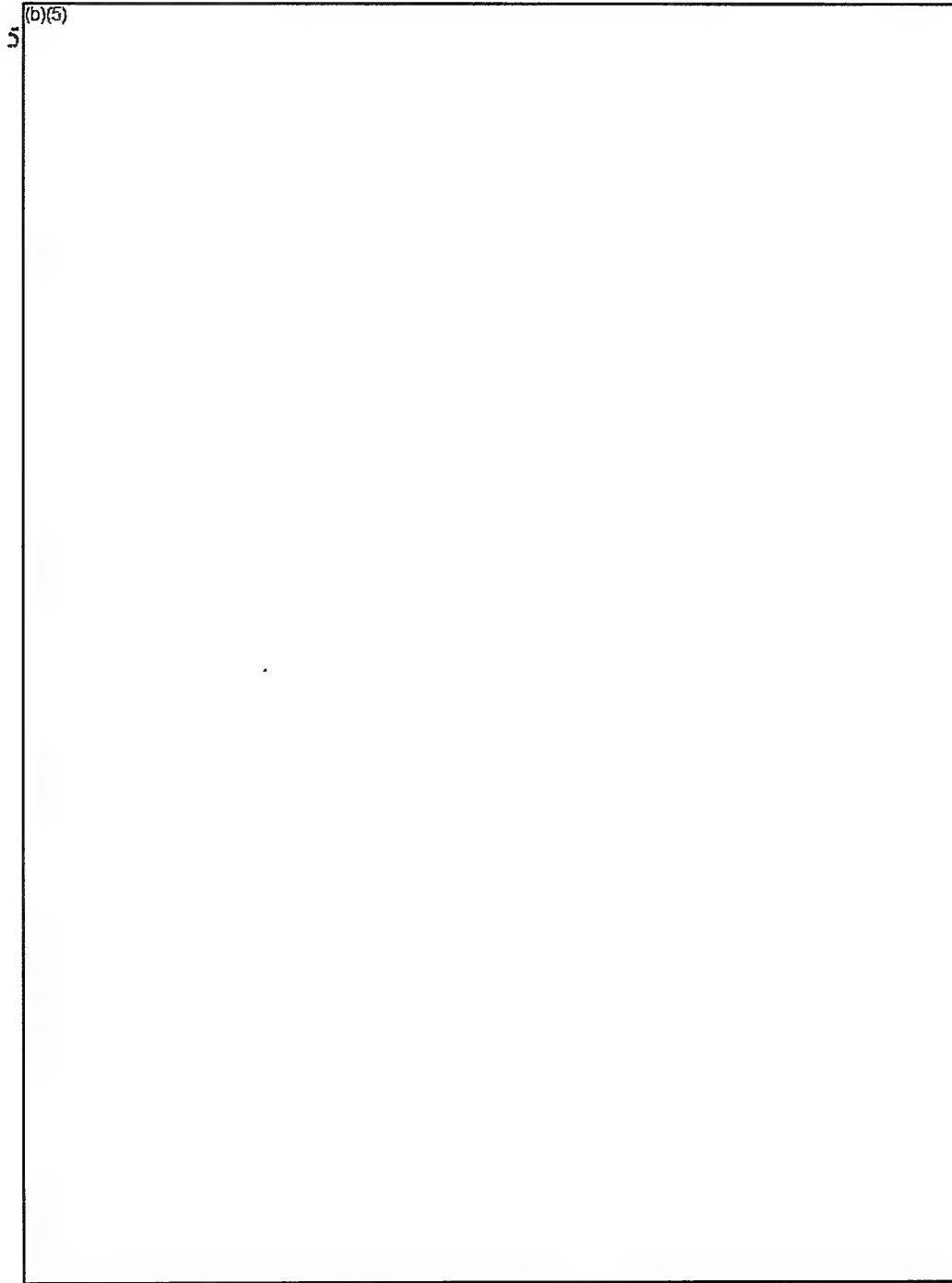
(Major Mod)	Generation of Therapeutic Human Anti-Influenza Virus Antibodies (HAIVA) using DRAG Mice
(Closing)	Biomarkers for Detection of Heat Intolerance in Mice
(1 <sup>st</sup> Annual)	Establishment and/or Maintenance of a Breeding Colony of Transgenic Mice
(2 <sup>nd</sup> Annual)	Molecular and Anatomical Effects of Circadian Disruption on the Stress Axis ( <i>Mus musculus</i> )
(2 <sup>nd</sup> Annual)	Pathogenesis of <i>Bacillus</i> Sterne and <i>Bacillus cereus</i> G9241 in Mice
(1 <sup>st</sup> Annual)	The Ubiquitin Proteasome System as a Therapeutic Target for Mouse TBI
(1 <sup>st</sup> Annual)	Advancing Gametocytocidal Agents as Antimalarial Drugs in Mice
(1 <sup>st</sup> Annual)	Maintenance of a Breeding Colony of Heterozygous Deletion of NFAT5 (TonEBP) Mice
(2 <sup>nd</sup> Annual)	Establishment and/or Maintenance of a Breeding Colony of: (1) HLA-DR4, RAG2KO, IL2RgcKO, CD80, NOD; (2) HLA-DR4, A2, RAG2KO, IL2RgcKO, NOD; (3) HLA-DR4, AD, RAG2KO, AbbKO, C57; (4) HLA-DR4, AbbKO, NOD
(2 <sup>nd</sup> Annual)	Translational Imaging Facility Protocol Development and Methods Validation for Mice, Rats, and Ferrets
(1 <sup>st</sup> Annual)	Host Response to and Virulence Properties of Enteropathogenic <i>Escherichia coli</i> (Mice)

3. The following animal study protocols were approved by Full Committee Review during this meeting:

None.

4. The following animal study protocols were denied approval by Full Committee Review during this meeting:

None.



B. Minor Modifications Approved Since Last Meeting.

The following minor modifications were approved by the Attending Veterinarian or the IACUC Administrator since the last meeting:

(b)(2)

- |                    |  |
|--------------------|--|
| (Change Procedure) | Induction of Tolerance to FVIII in Hemophilia in Mice  |
| (Change Procedure) | Ultrasound and Microbubble-Mediated Antibiotic Treatment of Osteomyelitis in Rats ( <i>Rattus norvegicus</i> )                   |
| (Add Personnel)    | Cognition and Memory in Rats ( <i>Rattus norvegicus</i> ): Impact of Various Diets: Ketones, Low Carbohydrate, and Low Fat Diets |
| (Add Personnel)    | Mechanisms and Therapy of Traumatic Brain Injury in Mice and Rat   |
| (Add Personnel)    | Effect of BMP-2 on Inflammatory and Nociceptive Signaling in Rat PNS and CNS   |
| (Add Personnel)    | Gene Therapeutic Approach for Tolerance Induction to Cognate Antigens and EAE in Mice  |
| (Add Personnel)    | Establishment and/or Maintenance of a Mice Breeding Colony for Analysis to Tolerance in EAE                                      |
| (Add Personnel)    | Induction of Tolerance to FVIII in Hemophilia in Mice  |
| (Add Personnel)    | Establishment and/or Maintenance of a Breeding Colony of Mice for Hemophilia Research  |
| (Add Animals)      | Regulation of Anti-Infectious Immunity (Mice)  |
| (Add Animals)      | Regulation of Anti-Infectious Immunity (Mice)  |
| (Add Personnel)    | Modulation of the Endocannabinoid System in Traumatic Brain Injury (Mouse and Rat)   |

- C. Approval of the following conveyances of grants to current protocols was reported to the IACUC.

(b)(2)

Gene Therapeutic Approach for Tolerance Induction to Cognate Antigens and EAE in Mice

Immune Responses to *Litomosoides sigmondontis* (obtained from Mongolian Jirds) in Mice

Establishment and Maintenance of the *Litomosoides sigmondontis* Lifecycle in Jirds (*Meriones unguiculatus*)

Establishment of a Disease Model of Lymphatic Filariasis (Ferrets, *Mustela putorius furo*)

- D. Training article: Policy 005 – Quarantine and Stabilization of Incoming Animals: Discussion of this policy was tabled. (b)(5)

(b)(5)

- E. Training article: Policy 008 – Laboratory Animal Exercise and Environmental Enrichment Program: Discussion of this policy was tabled (b)(5)

(b)(5)

- F. Training article: Policy 025 – Film, Videotaping and Audio Recordings of Animal Use in Research and Teaching at USU: Discussion of this policy was tabled. (b)(5)

(b)(5)

#### VI. New Business:

- G. New EIRB System (b)(6) provided an update regarding the status of training and

(b)(5)

- H. Update on Unexpected Deaths: At the November IACUC meeting, the LAM Director reported a non-compliance incident that occurred under protocol (b)(2) A

subcommittee was appointed by the Chair to further investigate the issue. A member of the subcommittee presented an overview of the non-compliance issue and the results of the subcommittee's investigation as well as their recommendations. The committee discussed the incident and the subcommittee recommendations. (b)(5)

(b)(5)

- I. Training article: Policy 012 – USDA Pain Category Determination: The policy was presented to the committee. Discussion of this policy was tabled. (b)(5)
- J. CAF Inspection: The Central Animal Facility (CAF) areas were inspected. It was noted that the water maze in the rat behavior room (b)(2) was rusted. Also, two minor issues were noted on the IACUC records inspection; both issues have resolutions pending.
- K. ACURO Inspection: A facility inspection was conducted by the Animal Care and Use Review Office (ACURO). Minor findings were reported and these have been resolved already.
- L. FOIA Request (b)(6) reported that a Freedom of Information Act (FOIA) request was received from People for the Ethical Treatment of Animals (PETA) for USUHS live tissue training studies.

A motion to close the meeting was approved at 1455.

VII. The next IACUC meeting is scheduled for (b)(2)

Next Site Visits: APG, SUR, PMB

Scheduled Laboratory Inspectors: 30, 2, 24, one volunteer

**December 15, 2016 IACUC Meeting Minutes**

Submitted by:

(b)(6)

Vice Chair, Institutional Animal Care and Use  
Committee, USUHS

Reviewed and Accepted by:

(b)(6)

Institutional Official, Animal Care and Use  
Program, USUHS



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD  
BETHESDA, MARYLAND 20814-4799



Institutional Animal Care and Use Committee

(b)(6)

January 18, 2017

MEMORANDUM FOR RECORD

SUBJECT: Minutes of the Institutional Animal Care and Use Committee of the Uniformed Services University of the Health Sciences Meeting (b)(5)

I. Under the provisions of USUHS Instruction 3204, a meeting of the Institutional Animal Care and Use Committee (IACUC) was held on January 18, 2017, in (b)(2). The purpose of the meeting was to review animal care and welfare issues. A memorandum detailing the meeting agenda was distributed on January 11, 2017. Dr. (b)(6) Chair, called the meeting to order at 1305.

II. Attendance:

A. Voting members present:

\* Member Numbers: 5, 7, 8, 13, 21, 23, 25, 30, 32

B. Voting member(s) absent:

\* Member Numbers: 1, 2, 3, 4, 9, 11, 16, 19

C. Non-Voting members present:

\* Member Number: 10, 39

D. IACUC staff member(s) present:

\* Member Numbers: 38, 41, 42

E. Guests:

\* None

III. Full Committee Review(s):

None.

IV. Minutes.

A. The December 15, 2016, IACUC meeting minutes were approved by voice vote of the committee (8-0-1\*).

\* Abstaining member was not present for the December 15, 2016 meeting.

V. Old Business.

A. Review of Animal Study Protocols.

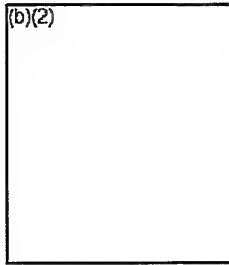
1. These protocols received significant, detailed review by the IACUC prior to the meeting. A motion for approval of the protocols listed below was made, seconded, and passed by voice vote:

None.

2. The following animal study protocols were approved via DMR before the meeting:

(b)(2)	(Major Mod)	Animal Model for Product Testing (Mouse)
	(Major Mod)	Animal Model for Product Testing (Mouse)
	(Initial)	Establishment and/or Maintenance of a Breeding Colony of KdM5b Conditional Knockout, Nestin Cre-Recombinase and Reporter Gene Transgenic Mice
	(Triennial)	Biomarkers for Detection of Heat Intolerance in Mice
	(2 <sup>nd</sup> Annual)	The Role of Neurogenin 1 in Mouse Cerebellar Development
	(Closing)	Establishment and Maintenance of Mouse Breeding Colonies of Kidney Collecting Duct-Specific Deletion of SHP-1
	(2 <sup>nd</sup> Annual)	Evaluation of the Effects of Multiple Blast- or Concussive-Brain Injuries on Neuropathological and Behavioral Outcomes in Male and Female Mice ( <i>Mus musculus</i> )
	(Closing)	Development of Normative Data for Behavior Testing in the CNRM Mouse Behavioral Assessment Core
	(Closing)	Establishment and Maintenance of a Breeding Colony of GATA-Low C5BL/6 Mice
	(Closing)	Role of MicroRNAs in Mild Traumatic Injury and Posttraumatic Stress Disorder: Identification of Biomarkers and Therapeutic Targets in Mice
	(2 <sup>nd</sup> Annual)	Analysis of ABLV and Rabies Virus Infection in a Mouse Model





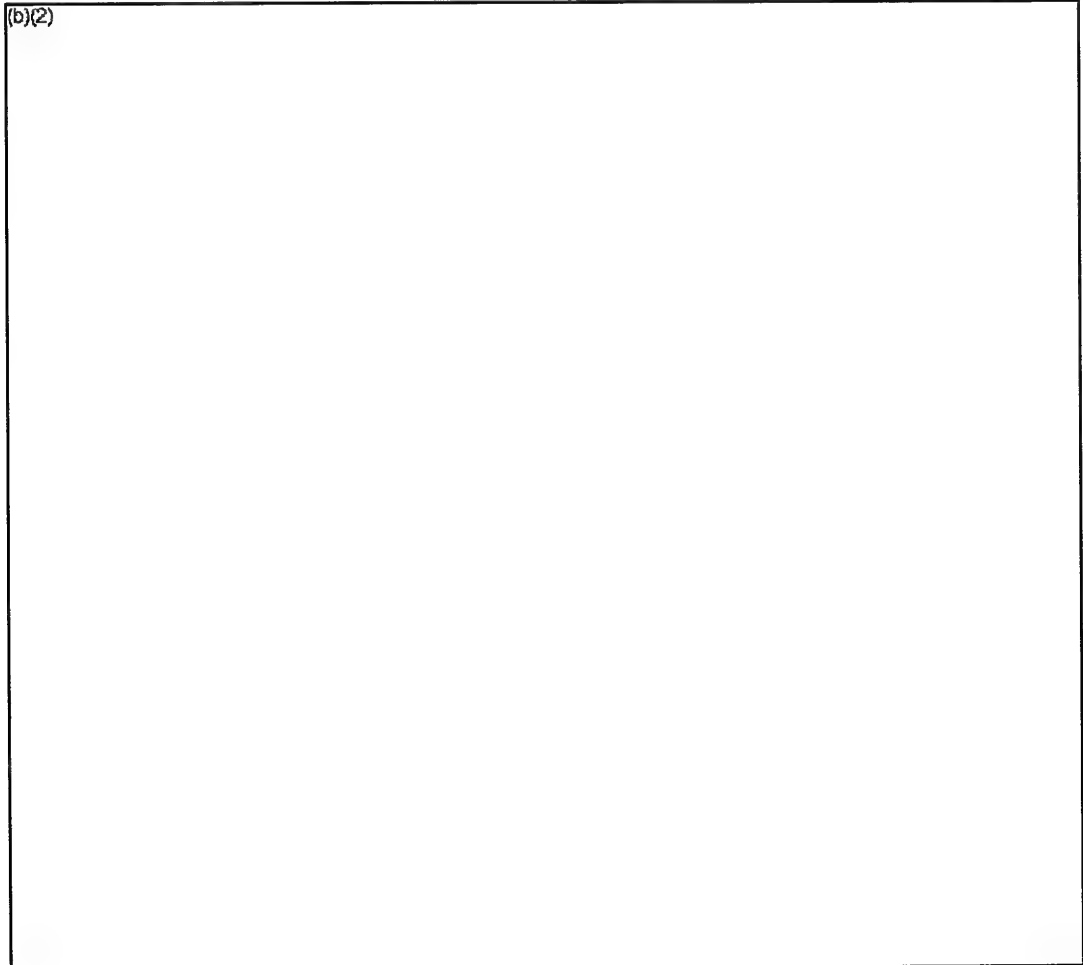
(Initial)

A Pilot Study of the CHIMERA (Closed-Head Impact Model of Engineered Rotational Acceleration) Device as a New Mouse Model of Traumatic Brain Injury

(Major Mod)

Role of Aquaporin-3 in Experimental Autoimmune Encephalomyelitis (Mice)

3. The following animal study protocols were approved by Full Committee Review during this meeting:  
  
None.
4. The following animal study protocols were denied approval by Full Committee Review during this meeting:  
  
None.
5. The following animal study protocols remain pending and are under active review:



(b)(2)

**B. Minor Modifications Approved Since Last Meeting.**

The following minor modifications were approved by the Attending Veterinarian or the IACUC Administrator since the last meeting:

(b)(2)

- |                      |  |
|----------------------|--|
| (Add Personnel)      | Blast TBI's Effect on the Stress Axis ( <i>Mus musculus</i> )  |
| (Change Procedures)  | <i>Enterococcus faecalis</i> Virulence, Persistence, and Adaptation (Rabbit)                           |
| (Add Personnel)      | Investigation of Traumatic Brain Injury in the Ferret Using Advanced MRI and Histopathology Techniques |
| (Add Strain/animals) | Establishment and Maintenance of Mouse Kidney Epithelial Cell-Specific Knockouts                       |

(b)(2)

- (Add Procedure) Inhibition of Endocannabinoid Hydrolysis in Sleep Disorder Associated with PTSD in Mice (*Mus musculus*) and Rats (*Rattus norvegicus*)
- (Change Procedure) Long-Term Neurobehavioral and Neuropathological Outcome of Repeated Exposure to Pure Primary Blast vs. Primary Blast in Combination with Blast-Induced Acceleration in Rat
- (Change Procedure) *Enterococcus faecalis* Virulence, Persistence, and Adaptation (Rabbit)
- (Add Procedure) Development of an Anti-Fibrotic, Remodeling Drug Therapy for Myelofibrosis (murine)
- (Add Personnel) 3,3'-Diindolylmethane Protection from Radiation-Induced Lung and Skin Injuries in a Murine Model (*Mus musculus*)
- (Add Personnel) Development of Captopril for the Mitigation of Delayed Lung Injuries from Ionizing Radiation in Mice (*Mus musculus*)
- (Add Personnel) Development of Captopril for the Mitigation of Acute Injuries from Ionizing Radiation in Gottingen Minipigs (*Sus scrofa domestica*)
- (Add Personnel) Investigation of Traumatic Brain Injury in the Ferret Using Advanced MRI and Histopathology Techniques
- (Add Strain/animals) Neurophysiology of Escalation of Aggression in a Rat Model of PTSD

C. Approval of the following conveyances of grants to current protocols was reported to the IACUC.

(b)(2)

Immune Responses to *Litomosoides sigmondontis* (obtained from Mongolian Jirds) in Mice

Establishment and Maintenance of the *Litomosoides sigmondontis* Lifecycle in Jirds (*Meriones unguiculatus*)

(b)(2)

Analysis of TCR and BCR Signaling to NF-kB in Gene Knockout Backgrounds (Mice)

Analysis of the Role of the Immune System and NF-kB Signaling in a Mouse Model of Traumatic Brain Injury (TBI)

Analysis of Immune Cell Responses in a Mouse Model of Lung Cancer

Analysis of ABLV and Rabies Virus Infection in a Mouse Model

Establishment and/or Maintenance of a Breeding Colony of Inbred, Transgenic and Knockout Mice Relating to Studies of NF-kB Activation

Investigation of Traumatic Brain Injury in the Ferret Using Advanced MRI and Histopathology Techniques

Animal Model for Product Testing (Mouse)

D. Training article: Policy 005 – Quarantine and Stabilization of Incoming Animals: The

(b)(5)

E. Training article: Policy 008 – Laboratory Animal Exercise and Environmental Enrichment Program: (b)(5)

(b)(5)

F. Training article: Policy 025 – Film, Videotaping and Audio Recordings of Animal Use in Research and Teaching at USU: The revised policy was approved by unanimous vote (9-

(b)(5)

G. Training article: Policy 012 – USDA Pain Category Determination: This policy document was reviewed. (b)(5)

(b)(5)

(b)(5)

also was agreed that the document should make it clear that Principal Investigators (PIs), veterinarians, and/or IACUC reviewers should propose alternative pain/distress categories for any of the listed examples if an alternative category was more appropriate in the context of a specific study. (b)(5)

(b)(5)

#### VI. New Business:

H. New EIRB System: (b)(6) provided an update regarding the status of training and

(b)(5)

I. Update on Unexpected Deaths: A report from an Investigation Subcommittee for an incident involving unexpected deaths of mice that occurred in November 2016 was discussed at the December meeting; however, no formal vote on the recommendations of the subcommittee was taken at that time. (b)(5)

(b)(5)

(b)(5)

The Committee voted unanimously (9-0-0) to approve the recommendations of the subcommittee.

J. Training Article: New Policy - Procedure for Evaluating and Reporting Protocol Deviations or Animal Welfare Concerns: A first draft of a proposed policy document was

(b)(5)

K. Inspections: The SUR inspections and a portion of the APG inspections were completed. No major issues were reported. Inspections for the remaining APG areas have been rescheduled.

L. AFRRRI – USU Collaboration during Animal Facility Renovations:

(b)(2)

(b)(2)

A motion to close the meeting was approved at 1418.

VII. The next IACUC meeting is scheduled for (b)(2)

Next Site Visits: APG, ANE, BIO

Scheduled Laboratory Inspectors: 9, 14, 15, 21

**January 18, 2017 IACUC Meeting Minutes**

Submitted by:

(b)(6)

Chair, Institutional Animal Care and Use  
Committee, USUHS

Reviewed and Accepted by:

(b)(6)

Institutional Official, Animal Care and Use  
Program, USUHS

## Appendix 9: IACUC/OB Protocol Form

Please attach a blank copy of form(s) used by the IACUC/OB to review and approve studies; include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.





## **USUHS Form 3206- Animal Study Proposal Form Instructions**

### **USUHS / DOD – SPONSORED ANIMAL RESEARCH PROPOSALS MUST USE THIS STANDARDIZED FORMAT**

*Reference DOD Directive 3216.1 & USUHS Instruction 3203*

\*\*\*\*\*

***Specific information requested in the following animal-use protocol template is a result of requirements of the Animal Welfare Act regulations (AWAR), the Guide for the Care and Use of Laboratory Animals, and other applicable Federal regulations and DOD directives.***

\*\*\*\*\*

This document is intended to be an aid in the preparation of a USUHS DOD – sponsored animal use proposal. The instructions and written explanations provided for individual paragraphs (ref. animal-use protocol template in AR 40-33 / USUHSINST 3203, Appendix C) are coded as hidden text. To see the instructions and examples for each section, select the "Show/Hide ¶" button on your tool bar. To print the hidden text, select "Print" on the drop down file menu. Under the "Options" button, select "Hidden text" under the "Include with document" section. Use of a word processor makes completion of this template a "fill-in-the-blanks" exercise. Please provide all response entries in the following font: Arial, Regular, 12, Black. Please do NOT submit this page of instructions with your animal protocol submission.

With the exception of title headings, each paragraph and subparagraph in the following template must have a response. Portions of the template that are not applicable to your particular protocol, (i.e. no surgery or no prolonged restraint) should be marked "N/A". There are no space limitations for the responses. Do not delete any sections.

Pertinent standing operating procedures or similar documents that are readily available to your IACUC may be referenced to assist in the description of specific procedures. It is critical that only animal studies or procedures documented in an IACUC – approved protocol be performed at your facility. Additionally, Principal Investigators, or other delegated research personnel, should keep accurate experimental records and be able to provide an audit trail of animal expenditures and use that correlates to their approved protocol.

**USUHS FORM 3206 ANIMAL STUDY PROPOSAL  
PROTOCOL COVER SHEET**

**PROTOCOL NUMBER:**

**PROTOCOL TITLE:**

**GRANT TITLE (if different from above):**

**USUHS PROJECT NUMBER/ DAI GRANT NUMBER:**

**FUNDING AGENCY:**

**EARLIEST ANTICIPATED FUNDING START DATE:**

**PRINCIPAL INVESTIGATOR:**

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Department

\_\_\_\_\_  
Office/Lab Telephone

\_\_\_\_\_  
Date

**SCIENTIFIC REVIEW:** This animal use proposal received appropriate peer scientific review and is consistent with good scientific research practice.

\_\_\_\_\_  
Research Unit Chief / Dept. Head Signature  
Typed Name:

\_\_\_\_\_  
Title

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Date

**STATISTICAL REVIEW:** A person knowledgeable in biostatistics reviewed this proposal to ensure that the number of animals used is appropriate to obtain sufficient data and/or is not excessive, and the statistical design is appropriate for the intent of the study,

\_\_\_\_\_  
Statistician Signature  
Typed Name:

\_\_\_\_\_  
Department

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Date

**ATTENDING VETERINARIAN:** In accordance with the Animal Welfare Regulations, the Attending Veterinarian was consulted in the planning of procedures and manipulations that may cause more than slight or momentary pain or distress, even if relieved by anesthetics or analgesics. All signatures are required prior to submission to the IACUC Office.

\_\_\_\_\_  
Attending/Consulting Veterinarian Signature  
Printed Name:

\_\_\_\_\_  
LAM

\_\_\_\_\_  
Department

\_\_\_\_\_  
Telephone

\_\_\_\_\_  
Date

The aims of the supporting grant must be submitted along with the 3206. If funding is from NIH please also submit the Vertebrate Animal Section (VAS).

**ANIMAL PROTOCOL NUMBER:**

**PRINCIPAL INVESTIGATOR:**

**PRINCIPAL INVESTIGATOR EMAIL:**

**ANIMAL PROTOCOL TITLE:**

**GRANT TITLE (if different from above):**

**USUHS PROJECT NUMBER:**

**DAI GRANT NUMBER:**

**CO-INVESTIGATOR(S):**

**TECHNICIANS(S):**

**I. NON-TECHNICAL SYNOPSIS:**

**II. BACKGROUND:**

**II.1. Background:**

**II.2. Literature Search for Duplication:**

**II.2.1. Literature Source(s) Searched:**

**II.2.2. Date of Search:**

**II.2.3. Period of Search:**

**II.2.4. Key Words and Search Strategy:**

**II.2.5. Results of Search:**

**III. OBJECTIVE/HYPOTHESIS:**

**IV. MILITARY RELEVANCE:**

**V. MATERIALS AND METHODS:**

**V.1. Experimental Design and General Procedures:**

**V.1.1. Experiment 1:**

**V.1.2. Experiment 2:**

**V.2. Data Analysis:**

**V.3. Laboratory Animals Required and Justification:**

**V.3.1. Non-animal Alternatives Considered:**

**V.3.2. Animal Model and Species Justification:**

**V.3.3. Laboratory Animals**

ALTERNATIVES CONSIDERATIONS: Does the protocol have any provisions that would qualify it to be identified as one that Refines, Reduces, or Replaces (3R's) the use of animals in relation to other protocols or procedures performed in the past?

Y/N (circle) **SECTION V.3.5.**

Exceptions to the *Guide for the Care and Use of Laboratory Animals* (Please check all applicable):

- ☐ Use of Paralytics (V.4.1.2.3.)
- ☐ Prolonged Restraint (V.4.2.)
- ☐ Multiple Major Survival Surgery (V.4.3.6.)
- ☐ Use of Non-pharmaceutical grade chemicals (V.4.4.1.)
- ☐ Use of Complete Freund's Adjuvant (V.4.4.3.)
- ☐ Death as an endpoint (V.4.5.)
- ☐ Food/Water Restriction (V.5.1.2.)
- ☐ Single Housing of Social Species (V.5.1.3)
- ☐ Restriction of Environmental Enrichment (V.5.3.2.)
- ☐ Drug Use/Controlled Substances (Appendix A)

IDENTIFICATION OF SPECIES AND STRAIN: In accounting for animal numbers, please ensure that the strain of animal as well as the species is identified. If more than one strain of any species will be used, please list each proposed strain in a separate column. If more than two species/strains are to be used, duplicate Sections V.3.3.1 – V.3.4 , and Section V.4.1.1.1, on subsequent pages to cover all requested strains.

	<u>Species/Strain #1</u>	<u>Species/Strain #2</u>
<b>V.3.3.1. <u>Genus &amp; Species:</u></b>		
<b>V.3.3.2. <u>Strain/Stock:</u></b>		
<b>V.3.3.3. <u>Source/Vendor:</u></b>		
<b>V.3.3.4. <u>Age:</u></b>		
<b>V.3.3.5. <u>Weight:</u></b>		
<b>V.3.3.6. <u>Sex:</u></b>		

**V.3.3.7. Special Considerations:**

**V.3.4. Number of Animals Required (by Species/Strain):**

**V.3.5. Refinement, Reduction, Replacement (3 Rs):**

**V.3.5.1. Refinement:**

**V.3.5.2. Reduction:**

**V.3.5.3. Replacement:**

**V.4. Technical Methods:**

**V.4.1. Pain / Distress Assessment:**

**V.4.1.1. APHIS Form 7023 Information:**

**V.4.1.1.1. Number of Animals:**

	<u>Species/Strain #1</u>	<u>Species/Strain #2</u>
V.4.1.1.1.1. <u>Column C:</u>		
V.4.1.1.1.2. <u>Column D:</u>		
V.4.1.1.1.3. <u>Column E:</u>		

**V.4.1.2. Pain Relief / Prevention:**

**V.4.1.2.1. Anesthesia/Analgesia/Tranquilization:**

**V.4.1.2.2. Pre- and Post-procedural (not surgery) Provisions:**

**V.4.1.2.3. Paralytics:**

**V.4.1.3. Literature Search for Alternatives to Painful or Distressful Procedures:**

**V.4.1.3.1. Sources Searched:**

**V.4.1.3.2. Date of Search:**

**V.4.1.3.3. Period of Search:**

**V.4.1.3.4. Key Words of Search:**

**V.4.1.3.5. Results of Search:**

**V.4.1.4. Unalleviated Painful or Distressful Procedure Justification:**

**V.4.2. Prolonged Restraint:**

**V.4.3. Surgery:**

**V.4.3.1. Pre-surgical Provisions:**

**V.4.3.2. Procedure:**

**V.4.3.3. Post-surgical Provisions:**

**V.4.3.4. Location:**

**V.4.3.5. Surgeon:**

**V.4.3.6. Multiple Major Survival Operative Procedures:**

**V.4.3.6.1. Procedures:**

**V.4.3.6.2. Scientific Justification:**

**V.4.4. Animal Manipulations:**

**V.4.4.1. Injections:**

**V.4.4.2. Biosamples:**

**V.4.4.3. Adjuvants:**

**V.4.4.4. Monoclonal Antibody (MAbs) Production:**

**V.4.4.5. Animal Identification:**

**V.4.4.6. Behavioral Studies:**

**V.4.4.7. Other Procedures:**

**V.4.4.8. Tissue Sharing:**

**V.4.5. Study Endpoint:**

**V.4.6. Euthanasia:**

**V.5. Veterinary Care:**

**V.5.1. Husbandry Considerations:** Except as noted below, routine animal husbandry will be provided in accordance with LAM Husbandry SOPs for each species in this protocol.

**V.5.1.1. Study Room:**

Building(s) \_\_\_\_\_ Room Number(s) \_\_\_\_\_

**V.5.1.2. Special Husbandry Provisions:**

**Food Restriction:** Yes \_\_\_\_\_ No \_\_\_\_\_

**Fluid Restriction:** Yes \_\_\_\_\_ No \_\_\_\_\_

**V.5.1.3. Exceptions:**

\_\_\_\_\_

**V.5.2. Veterinary Medical Care:**

**V.5.2.1. Routine Veterinary Medical Care:**

**V.5.2.2. Emergency Veterinary Medical Care:** All emergency, weekend, and holiday care is provided by two animal husbandry technicians, one or more veterinary technicians, and an on-call veterinarian. Essential husbandry procedures and health rounds are conducted by LAM personnel once daily during weekend and holidays.

**V.5.3. Environmental Enrichment:**

**V.5.3.1. Enrichment Strategy:** Except as indicated below, all animals on this protocol will be provided with routine environmental enrichment in accordance with LAM SOPs and IACUC Policies. Examples include nestlets and tunnels for rodents; balls, toys and food enrichment treats for large animal species.

**V.5.3.2. Enrichment Restrictions:**

**VI. STUDY PERSONNEL QUALIFICATIONS AND TRAINING:**

**STUDY PERSONNEL QUALIFICATIONS/TRAINING**

Protocol activity or procedure (e.g., tail vein injections, euthanasia)	Name of person performing activity	Experience of person performing activity (species specific) (e.g., research technician, 2 yrs experience)	Specific training in this activity or procedure (e.g., rodent handling class, 1999)	Dates of the (b)(2)

**VII. BIOHAZARDS/SAFETY:**

- A. Zoonotic Disease:**
- B. Safety Hazards:**
- C. Isoflurane:**
- D. Isoflurane Exposure:**
- E. Sharp Instruments:**
- F. Infectious Agents that do not cause Zoonoses:**

**VIII. ENCLOSURES:**



**IX. EXTRAMURAL COLLABORATION:**

If there are any collaborations with outside entities, please explain here.

**X. ASSURANCES:**

As the Principal Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

**A. Animal Use:** The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC prior to its implementation.

**B. Duplication of Effort:** I have made a reasonable, good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

**C. Statistical Assurance:** I assure that I have consulted with an individual who is qualified to evaluate the statistical design or strategy of this proposal, and that the "minimum number of animals needed for scientific validity are used."

**D. Biohazard\Safety:** I have taken into consideration and made the proper coordination regarding all applicable rules and regulations concerning radiation protection, biosafety, recombinant issues, and so forth, in the preparation of this protocol.

**E. Training:** I verify that the personnel performing the animal procedures / manipulations / observations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures / manipulations.

**F. Training:** I verify that I have attended the

(b)(2)

(b)(2)

Principal Investigator Signature

Date

**G. Training:** The following personnel will attend the next

(b)(2)

(b)(2)

**H. Responsibility:** I acknowledge the inherent moral, ethical and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to conduct this study in the spirit of the fourth "R" that the DOD has embraced, namely,

"Responsibility" for implementing animal use alternatives where feasible and conducting humane and lawful research.

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

**I. Painful Procedure(s):**

I am conducting biomedical experiments which may potentially cause more than momentary or slight pain or distress to animals. This potential pain and/or distress **WILL or WILL NOT** be relieved with the use of anesthetics, analgesics and/or tranquilizers. I have considered alternatives to such procedures; however, using the methods and sources described in the protocol, I have determined that alternative procedures are not available to accomplish the objectives of this proposed experiment.

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

**XI. PROTOCOL ABSTRACT:**

- A. Animal Protocol Number:**
- B. Animal Protocol Title:**
- C. Principal Investigator:**
- D. Performing Organization:**
- E. Funding:**
- F. Objective and Approach:**
- G. Indexing Terms (Descriptors):**

## **APPENDIX A.**

PI NAME:

PROTOCOL NUMBER:

### **DRUGS AND CONTROLLED SUBSTANCES**

Please list ALL drugs and controlled substances that will be used under this protocol, indicating the DEA Schedule if known. Provide both the Approved Name and the Proprietary Name of each drug if known.

This list, once approved, will be used by the IACUC and the USU Pharmacy to determine which drugs and controlled substances can be supplied to the Principal Investigator. The Pharmacy will not dispense to the PI any drug that is not included in this list.

Drug Name  
(Please give both approved and  
Proprietary Names if possible)

---

DEA Schedule (I, II, III, or IV)  
(if known)

---

- 1.
- 2.

Date of Protocol Expiration Date:

## Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.

136

8/16





UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES  
4301 JONES BRIDGE ROAD  
BETHESDA, MARYLAND 20814-4712



November 29, 2016

Memorandum for Dr. (b)(6) Institutional Officer (b)(6)

Subject: Semi-annual Inspection of USU Central Animal Facilities, November 16, 2016

The IACUC inspected the USU Central Animal Facility on November 16, 23, and 29, 2016.

The inspection team consisted of:

Members #23 and 24 – Small Animals – Group A  
Members #1 and 23 – Small Animals – Group B  
Members #17 and 21 – Large Animals/VMD Animal Records  
Members #11 and 32 – Satellite Suite and Surgery  
Members #30 and 39 – IACUC Records  
Members #9 and 25 – Barrier and Physical Plant and LAM Transport Van

Procedures: Inspectors noted problems and deficiencies in each area. Whenever possible Center for Laboratory Animal Medicine (LAM) staff corrected minor deficiencies immediately. Problems that could not be corrected on the day of the inspection were noted; LAM staff or Principal Investigators determined the most appropriate corrective action, and these will be implemented as soon as possible. Work orders will be placed with Facilities for items that require their action.

The attached tables details the problems and deficiencies that were noted, the actions that have been taken, with the date on which the action was completed. A few deficiencies are still awaiting further action. Issues from the previous CAF inspection have all been resolved.

The laboratories outside of the Central Animal Facility have been inspected semi-annually throughout the year by members of the IACUC.

No minority reports were expressed by the committee members.

The departures from the USDA Animal Welfare Regulation, The Guide and the PHS Policy are attached.

All noted problems and deficiencies were brought to the attention of IACUC members and discussed at a scheduled IACUC meeting after the inspection.

Signed,

(b)(6)

(b)(6)

Chair, Institutional Animal Care and Use  
Committee, USUHS

# I. Semiannual Program Review and Facility Inspection Report

Date: 18 MAY 2016

Members in Attendance: 1, 9, 11, 21, 23, 24, 25, 30, 32, 39

Deficiency Category*	✓	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date Complete
M			Ceiling needs repair	AHD	Work order submitted on 5 Dec 2016	
M			Chemical is unlabeled, on floor and not in a spill proof container MB-10 out of date, needs new bottle No recent room check Freezer needs log/thermometer	VMD	Corrected on the spot (COTS) on 5 Dec 2016	5 Dec 2016
S			Equipment & materials need to be removed from lab. Bupivacaine and saline both expired and left out.	Capacchione (left USU)	Emailed Department to Equipment see how owns equipment and supplies on 5 Dec 2016	taken over by Dept Chair 7 Dec 2016
M			Repeat observation. A system to communicate pilot studies is not yet in place. Recommended corrective actions: 1) Add language to annual review that specifically addresses pilot study results. 2) Add language to new protocols specifically addressing prior studies, such as: 1) Is this protocol based on a USUHS-approved pilot study? If yes, please include a discussion of the pilot findings in the protocol (Background section?). Repeat observation. Need training on how to perform CAF.	IACUC	21 November 2016	22 November 2016
M		(b)(2)	Recommended corrective action: Use the AALAS Learning Library facility inspection module.			



(b)(2)

M	Identify method to track open findings from each CAF inspection.	IACUC	21 November 2016	22 November 2016
M	Recommended action: Add CAF findings to IACUC agenda for discussion/updates on any open items.			
M	Light is out.	AHD	COTS -- 5 Dec 2016	5 Dec 2016
M	Chuck pad needs changing	PI	Corrected by PI last week	5 Dec 2016
M	Trash can has no cover	AHD	COTS -- 5 Dec 2016	5 Dec 2016
M	Shavings on chair and work area	PI	Corrected by PI last week	5 Dec 2016
M	Full syringe unlabeled in box			
M	Weather stripping on door needs to be fixed	AHD	Inspection by facilities found no defect in door	5 Dec 2016
	One cage low on H2O and food wedged under bottle	PI	Emailed PI about using something other than food -- on 5 Dec 2016	

M		No water available/ bucket overturned/ puddle of water in corner No vermin trap	AHD	Water buckets are for enrichment – not primary water – have Lixits- COTS 5 Dec 2016	5 Dec 2016
M		T Maze has rust like material	PI	Vermin traps are not used in large animal rooms due to sanitation routine of spraying down floors with water	
M		Quatricide has no date logbook is not current	AHD VMD	Emailed PI to have maze cleaned COTS – 5 Dec 2016 COTS – 5 Dec 2016	5 Dec 2016
M		No vermin trap	AHD	Contacting pest control company to see if room is covered by contract – 5 Dec 2016	
M		Cardboard box on cart	AHD	COTS – 5 Dec 2016	5 Dec 2016
M		Rat cages do not have enrichment objects	AHD	COTS – 5 Dec 2016	5 Dec 2016
M		Cardboard box on floor	AHD	COTS – 5 Dec 2016	5 Dec 2016

(b)(2)

M Multiple Humidity outside of acceptable range AHD

(b)(2)

Work order placed for HVAC on 5 Dec 2016

M (b)(2) Water maze bath tub is rusty and paint is peeling. PI

PI was emailed

- \* A = acceptable
- M = minor deficiency
- S = significant deficiency (is or may be a threat to animal health or safety)
- C = change in program (PHS Policy IV.A.1.a.-1.) (include in semiannual report to IO and in annual report to OLAW)
- NA = not applicable
- ✓ Check if repeat deficiency

DOD SEMIANNUAL PROGRAM REVIEW/ FACILITY INSPECTION CHECKLIST				
ORGANIZATION	DATE OF REVIEW (YYYYMMDD)			
Uniformed Services University of the Health Sciences	2016NOV29			
Completion of this checklist by the IACUC during the semi-annual program review and facility inspection is mandatory. Mark X in the most appropriate category for each item. KEY: A = Acceptable, M = Minor deficiency, S = Significant deficiency (is or may be a threat to animal health or safety). Reference The Guide for the Care and Use of Laboratory Animals, 8th edition, for category details.				
CATEGORIES	A	M	S	N/A
<b>SECTION I - ANIMAL CARE AND USE PROGRAM</b>				
<b>1. PROGRAM MANAGEMENT</b>				
a. PROGRAM MANAGEMENT RESPONSIBILITY	X			
(1) The Institutional Official	X			
(2) The Attending Veterinarian	X			
(3) The Institutional Animal Care and Use Committee	X			
(4) Collaborations	X			
b. PERSONNEL MANAGEMENT	X			
(1) Training and Education	X			
(a) Veterinary and Other Professional Staff	X			
(b) Animal Care Personnel	X			
(c) The Research Team	X			
(d) The IACUC		X		
(2) Occupational Health and Safety of Personnel	X			
(a) Control and Prevention Strategies	X			
(b) Hazard Identification and Risk Assessment	X			
(c) Facilities, Equipment, and Monitoring	X			
(d) Personnel Training	X			
(e) Personal Hygiene	X			
(f) Animal Experimentation Involving Hazards	X			
(g) Personal Protection	X			
(h) Medical Evaluation and Preventive Medicine for Personnel	X			
(3) Personnel Security	X			
(4) Investigating and Reporting Animal Welfare Concerns	X			
<b>2. PROGRAM OVERSIGHT</b>				
a. THE ROLE OF THE IACUC	X			
(1) IACUC Constitution and Function	X			
(2) Protocol Review	X			
(3) Special Considerations for IACUC Review	X			
(a) Experimental and Humane Endpoints	X			
(b) Unexpected Outcomes	X			
(c) Physical Restraint	X			
(d) Multiple Survival Surgical Procedures	X			
(e) Food and Fluid Regulation	X			
(f) Use of Non-Pharmaceutical Grade Chemicals and Other Substances	X			
(g) Field Investigations	X			
(h) Agricultural Animals	X			
b. POSTAPPROVAL MONITORING		X		
<b>3. DISASTER PLANNING AND EMERGENCY PREPAREDNESS</b>				
<b>SECTION II - ENVIRONMENT, HOUSING, AND MANAGEMENT</b>				
<b>4. TERRESTRIAL ANIMALS - ENVIRONMENT</b>				
a. MICROENVIRONMENT AND MACROENVIRONMENT	X			
b. TEMPERATURE AND HUMIDITY		X		
c. VENTILATION AND AIR QUALITY	X			
d. ILLUMINATION	X			
e. NOISE AND VIBRATION	X			

CATEGORIES	A	M	S	N/A
<b>SECTION II - ENVIRONMENT, HOUSING, AND MANAGEMENT (Continued)</b>				
<b>5. TERRESTRIAL ANIMALS - HOUSING</b>				
a. MICROENVIRONMENT (PRIMARY ENCLOSURE)	X			
b. ENVIRONMENTAL ENRICHMENT		X		
c. SHELTERED OR OUTDOOR HOUSING	X			
d. NATURALISTIC ENVIRONMENTS	X			
e. SPACE	X			
(1) General Considerations for All Animals	X			
(2) Laboratory Rodents	X			
(3) Other Common Laboratory Animals	X			
(4) Nonhuman Primates	X			
(5) Agricultural Animals	X			
<b>6. TERRESTRIAL ANIMALS - MANAGEMENT</b>				
a. BEHAVIORAL AND SOCIAL MANAGEMENT	X			
(1) Activity	X			
(2) Social Environment	X			
(3) Procedural Habituation and Training of Animals	X			
b. HUSBANDRY	X			
(1) Food	X			
(2) Water		X		
(3) Bedding and Nesting Materials	X			
(4) Sanitation		X		
(a) Bedding/Substrate Change	X			
(b) Cleaning and Disinfection of the Microenvironment		X		
(c) Cleaning and Disinfection of the Macroenvironment	X			
(d) Assessing the Effectiveness of Sanitation	X			
(5) Waste Disposal		X		
(6) Pest Control		X		
(7) Emergency, Weekend, and Holiday Care	X			
c. POPULATION MANAGEMENT	X			
(1) Identification	X			
(2) Recordkeeping	X			
(3) Breeding, Genetics and Nomenclature	X			
<b>7. AQUATIC ANIMALS - ENVIRONMENT</b>				
a. MICROENVIRONMENT AND MACROENVIRONMENT				X
b. WATER QUALITY				X
c. LIFE SUPPORT SYSTEM				X
d. TEMPERATURE, HUMIDITY, AND VENTILATION				X
e. ILLUMINATION				X
f. NOISE AND VIBRATION				X
<b>8. AQUATIC ANIMALS - HOUSING</b>				
a. MICROENVIRONMENT (PRIMARY ENCLOSURE)				X
b. ENVIRONMENTAL ENRICHMENT AND SOCIAL HOUSING				X
c. SHELTERED, OUTDOOR, AND NATURALISTIC HOUSING				X
d. SPACE				X
<b>9. AQUATIC ANIMALS - MANAGEMENT</b>				
a. BEHAVIORAL AND SOCIAL MANAGEMENT				X
b. HUSBANDRY				X
(1) Food				X
(2) Water				X
(3) Substrate				X
(4) Sanitation				X
(a) Cleaning and Disinfection of the Macroenvironment				X
(5) Waste Disposal				X
(6) Pest Control				X
(7) Emergency, Weekend, and Holiday Care				X
c. POPULATION MANAGEMENT				X
(1) Identification				X
(2) Aquatic Animal Recordkeeping				X

CATEGORIES	A	M	S	N/A
<b>SECTION III - VETERINARY CARE</b>				
<b>10. ANIMAL PROCUREMENT AND TRANSPORTATION</b>				
a. ANIMAL PROCUREMENT	X			
b. TRANSPORTATION OF ANIMALS	X			
<b>11. PREVENTIVE MEDICINE</b>				
a. ANIMAL BIOSECURITY	X			
b. QUARANTINE AND STABILIZATION	X			
c. SEPARATION BY HEALTH STATUS AND SPECIES	X			
d. SURVEILLANCE, DIAGNOSIS, TREATMENT, AND CONTROL OF DISEASE	X			
<b>12. CLINICAL CARE AND MANAGEMENT</b>				
a. MEDICAL MANAGEMENT	X			
b. EMERGENCY CARE	X			
c. RECORDKEEPING		X		
<b>13. SURGERY</b>				
a. TRAINING	X			
b. PRESURGICAL PLANNING	X			
c. SURGICAL FACILITIES	X			
d. SURGICAL PROCEDURES	X			
e. ASEPTIC TECHNIQUE		X		
f. INTRAOPERATIVE MONITORING	X			
g. POSTOPERATIVE CARE	X			
<b>14. PAIN AND DISTRESS</b>	X			
<b>15. ANESTHESIA AND ANALGESIA</b>	X			
<b>16. EUTHANASIA</b>	X			
<b>SECTION IV - PHYSICAL PLANT</b>				
<b>17. GENERAL CONSIDERATIONS</b>	X			
<b>18. FUNCTIONAL AREAS</b>	X			
<b>19. CONSTRUCTION GUIDELINES</b>				
a. CORRIDORS	X			
b. ANIMAL ROOM DOORS		X		
c. EXTERIOR WINDOWS	X			
d. FLOORS	X			
e. DRAINAGE	X			
f. WALLS AND CEILINGS		X		
g. HEATING, VENTILATION, AND AIR CONDITIONING	X			
h. POWER AND LIGHTING		X		
i. STORAGE AREAS		X		
j. NOISE CONTROL	X			
k. VIBRATION CONTROL	X			
l. FACILITIES FOR SANITIZING MATERIALS	X			
m. ENVIRONMENTAL MONITORING	X			
<b>20. SPECIAL FACILITIES</b>				
a. SURGERY	X			
b. BARRIER FACILITIES	X			
c. IMAGING	X			
d. WHOLE BODY IRRADIATION	X			
e. HAZARDOUS AGENT CONTAINMENT	X			
f. BEHAVIORAL STUDIES	X			
g. AQUATIC SPECIES HOUSING	X			
<b>21. SECURITY AND ACCESS CONTROL</b>	X			

# SECTION V - REMARKS

- 1.B.1.D. - M - (b)(2) Need training on how to perform CAF.  
 1.B.1.D. - M - (b)(2) Identify method to track open findings from each CAF inspection.  
 2.B. - M - (b)(2) - A system to communicate pilot studies is not yet in place.  
 4.B. - M - (b)(2) - Humidity outside of acceptable range  
 5.B. - M - (b)(2) No recent room check  
 5.B. (b)(2) - Rat cages do not have enrichment objects  
 6.B.2. - M - (b)(2) One cage low on H2O and food wedged under bottle  
 6.B.4. - M - Chemical is unlabeled, on floor and not in a spill proof container  
 6.B.4. - M - MB-10 out of date, needs new bottle  
 6.B.4. - M - Trash can has no cover  
 6.B.4. - M - Shavings on chair and work area  
 6.B.4. - M - T Maze has rust like material  
 6.B.4. - M - Quatricide has no date  
 6.B.4. - M - Water maze bath tub is rusty and paint is peeling  
 6.B.4.B. - M - No water available/ bucket overturned/ puddle of water in corner  
 6.B.5. - M - Full syringe unlabeled in box  
 6.B.5. - M - Cardboard box on cart  
 6.B.5. - M - (b)(2) - Cardboard box on floor  
 6.B.6. - M - No vermin trap  
 12.C. - M - Freezer needs log/thermometer  
 12.C. - M (b)(2) - Logbook is not current  
 13.E. - M - Chuck pad needs changing  
 19. B. - M - Weather stripping on door needs to be fixed  
 19.F. - M - Ceiling needs repair  
 19. H. - M - Light is out  
 19.I. - M - Equipment & materials need to be removed from lab.

All exceptions from the Guide have been approved by the IACUC Committee:

- Dr. (b)(2), (b)(6) Cage size  
 Dr. (b)(2), (b)(6) Cage size and single housing  
 Dr. (b)(2), (b)(6) Higher temperatures  
 Dr. (b)(2), (b)(6) Use of Non-Pharmaceutical Grade Chemicals  
 Dr. (b)(2), (b)(6) Multiple Major Survival Surgery  
 Dr. (b)(2), (b)(6) Single Housing of Social Animals  
 Dr. (b)(2), (b)(6) Use of Non-Pharmaceutical Grade Chemicals  
 Dr. (b)(2), (b)(6) Use of Non-Pharmaceutical Grade Chemicals  
 Dr. (b)(2), (b)(6) Use of Complete Freund's Adjuvant  
 Dr. (b)(2), (b)(6) Use of Complete Freund's Adjuvant  
 Dr. (b)(2), (b)(6) Single Housing of Social Animals, Restriction of Environmental Enrichment  
 Dr. (b)(2), (b)(6) Use of Non-Pharmaceutical Grade Chemicals  
 Dr. (b)(2), (b)(6) Use of Non-Pharmaceutical Grade Chemicals  
 Dr. (b)(2), (b)(6) Single Housing of Social Animals  
 Dr. (b)(2), (b)(6) Single Housing of Social Animals  
 Dr. (b)(2), (b)(6) Use of Non-Pharmaceutical Grade Chemicals, Single Housing of Social Animals, Restriction of Environmental Enrichment  
 Dr. (b)(6) (b)(2) Use of Non-Pharmaceutical Grade Chemicals

(b)(6)



(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

**Program Description**  
**Animal Care and Use Program**

**Center for Laboratory Animal Medicine**

**Uniformed Services University of the Health Sciences**

**4301 Jones Bridge Road**  
**Bethesda, MD 20814**

**<April 1, 2017>**

**For**  
**AAALAC International**

## Table of Contents

Section 1. Introduction .....	1
Section 2. Description.....	6
I. Animal Care and Use Program.....	6
A. Program Management.....	6
1. Program Management Responsibility .....	6
a. The Institutional Official .....	6
b. Role of the Attending Veterinarian.....	6
c. Interinstitutional Collaborations.....	9
2. Personnel Management .....	9
a. Training, Education, and Continuing Educational Opportunities.....	9
i. Veterinary and Other Professional Staff.....	10
ii. Animal Care Personnel .....	12
iii. The Research Team .....	13
b. Occupational Health and Safety of Personnel.....	15
i. Institutional Oversight.....	15
ii. Standard Working Conditions and Baseline Precautions .....	18
1) Medical Evaluation and Preventive Medicine for Personnel.....	18
2) Personnel Training Regarding Occupational Health and Safety .....	22
3) Personal Hygiene.....	23
4) Standard Personnel Protection .....	25
iii. Animal Experimentation Involving Hazards.....	30
B. Program Oversight.....	36
1. The Role of the IACUC/OB .....	36
a. IACUC/OB Composition and Function.....	36
b. Protocol Review.....	37
c. Special Considerations for IACUC/OB Review.....	41
i. Experimental and Humane Endpoints.....	41
ii. Unexpected Outcomes that Affect Animal Well-being.....	42



iii. Physical Restraint .....	42
iv. Multiple Survival Surgical Procedures.....	43
v. Food and Fluid Regulation .....	44
vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances .....	48
vii. Field Investigations .....	48
viii. Animal Reuse.....	48
2. Post-Approval Monitoring.....	49
3. Investigating and Reporting Animal Welfare Concerns .....	51
4. Disaster Planning and Emergency Preparedness.....	52
II. Animal Environment, Housing and Management.....	53
A. Animal Environment.....	53
1. Temperature and Humidity.....	53
2. Ventilation and Air Quality .....	54
3. Life Support Systems for Aquatic Species .....	55
4. Noise and Vibration.....	55
B. Animal Housing.....	55
1. Primary Enclosures .....	56
2. Environmental Enrichment, Social, and Behavioral Management.....	56
a. Environmental Enrichment .....	56
b. Social Environment.....	57
c. Enrichment, Social and Behavioral Management Program Review.....	57
d. Procedural Habituation and Training of Animals.....	58
e. Sheltered or Outdoor Housing .....	58
f. Naturalistic Environments.....	58
C. Animal Facility Management.....	59
1. Husbandry.....	59
a. Food .....	59
b. Drinking Water.....	61
c. Bedding and Nesting Materials.....	61

d. Miscellaneous Animal Care and Use Equipment.....	62
e. Sanitation .....	63
i. Bedding/Substrate Change .....	63
ii. Cleaning and Disinfection of the Micro- and Macro-Environments.....	64
f. Conventional Waste Disposal.....	65
g. Pest Control.....	65
h. Weekend and Holiday Animal Care.....	67
2. Population Management .....	67
a. Identification .....	67
b. Breeding, Genetics, and Nomenclature.....	68
III. Veterinary Care .....	69
A. Animal Procurement and Transportation .....	69
1. Animal Procurement.....	69
2. Transportation of Animals .....	70
B. Preventive Medicine.....	70
1. Animal Biosecurity.....	70
2. Quarantine and Stabilization .....	71
3. Separation by Health Status and Species.....	72
C. Clinical Care and Management.....	73
1. Surveillance, Diagnosis, Treatment and Control of Disease .....	73
2. Emergency Care .....	75
3. Clinical Record Keeping .....	75
4. Diagnostic Resources .....	76
5. Drug Storage and Control .....	77
D. Surgery .....	77
1. Pre-Surgical Planning.....	77
2. Surgical Facilities .....	78
3. Surgical Procedures.....	79
4. Aseptic Technique.....	79
5. Intraoperative Monitoring.....	81

6. Postoperative Care .....	81
E. Pain and Distress.....	82
F. Anesthesia and Analgesia .....	82
G. Euthanasia.....	84
IV. Physical Plant.....	85
A. Facilities Overview.....	86
B. Centralized (Centrally-Managed) Animal Facility(ies) .....	86
C. Satellite Animal Housing Facilities .....	88
D. Emergency Power and Life Support Systems.....	89
1. Power.....	89
2. Other System Malfunctions. ....	89
E. Other Facilities.....	89
1. Other Animal Use Facilities .....	89
2. Other Animal Program Support Facilities .....	90

## Appendices

Appendix 1:	Glossary of Abbreviations and Acronyms
Appendix 2:	Summary of Animal Housing and Support Sites
Appendix 3:	Line Drawings
Appendix 4:	Organizational Chart(s)
Appendix 5:	Animal Usage
Appendix 6:	Personnel Medical Evaluation Form
Appendix 7:	IACUC/OB Membership Roster
Appendix 8:	IACUC/OB Minutes
Appendix 9:	Blank IACUC/OB Protocol Form
Appendix 10:	IACUC/OB Periodic Report
Appendix 11:	Heating, Ventilation and Air Conditioning (HVAC) System Summary
Appendix 12:	Aquatic Systems Summary – Part I & II
Appendix 13:	Primary Enclosures and Animal Space Provisions
Appendix 14:	Cleaning and Disinfection of the Micro- and Macro-Environment
Appendix 15:	Facilities and Equipment for Sanitizing Materials
Appendix 16:	Lighting Summary
Appendix 17:	Satellite Housing Facilities

## Program Description

### Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

#### Section 1. Introduction

- A. State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

The Uniformed Services University of the Health Sciences (USUHS) was authorized by the United States Congress on 21 September 1972 (IAW Public Law 92-426) and the F. Edward Hebert School of Medicine was funded shortly thereafter. Each medical school class consists of approximately 171 men and women who are commissioned officers in the United States Army, Navy, Air Force, or Public Health Service, and serve in their respective services upon graduation.

The principal components of the University are the School of Medicine, the Graduate School of Nursing, and the Postgraduate Dental College. There are 25 academic departments in the School of Medicine and eight in the Graduate School of Nursing. A Graduate school offers both Masters and Doctoral programs in all of the University's basic science departments, and the Graduate School of Nursing.

- B. Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

USUHS is the Nation's federal health services university and is committed to excellence in military medicine and public health during peace and war. It provides the Nation with health professionals dedicated to career service in the Department of Defense and the United States Public Health Service and with scientists who serve the public good. It serves the uniformed services and the Nation as an outstanding academic health sciences center with a worldwide perspective for education, research, service, and consultation; it is unique in relating these activities to military medicine, disaster medicine, and military medical readiness. While the University's principal focus is medical education, USUHS also conducts basic science and clinical research programs, offers graduate medical education leading to a M.P.H., M.S., or Ph.D. degree, and sponsors a vigorous and growing continuing medical education program. The University's research and teaching programs that use animals involve all disciplines of biomedical and behavioral sciences that are required to meet the above mentioned objectives.

The animal care and use program is instrumental in achieving the university's mission of educating health professionals and serving as a research institution for military medicine. Animals are used in training labs for physicians and as various research models. The animal

care and use program oversees animal welfare and ensures only high quality animals are maintained under appropriate conditions to reduce experimental variables and provide valid, scientific data. The Center for Laboratory Animal Medicine (LAM) is responsible for the humane care, use, and welfare of research animals, in accordance with all federal and Department of Defense (DoD) regulations and guidelines, the Guide for the Care and Use of Laboratory Animals, as well as USUHS Instruction 3204, "The Use of Animals in the USUHS." Oversight of the Animal Care and Use Program (ACUP) is provided by the Institutional Animal Care and Use Committee (IACUC).

- C. Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals (Guide)*, NRC, 2011; *the Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide)*, FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

USUHS maintains an OLAW Assurance (A3448-01). Thus, the Guide for the Care and Use of Laboratory Animals, NRC, 2011, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the Animal Welfare Act regulations are used to govern the animal care and use program. As a DoD institution, the ACUP must adhere to the regulatory requirements in DoD Instruction 3216.01 "Use of Animals in DoD Programs" and USUHSINST 3203 "The Care and Use of Laboratory Animals in DoD Programs"

- D. Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note: For individuals whose information is publically available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.*), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care

programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

The lines of authority for the University are defined in the organizational charts for USUHS and LAM (Appendix 4). Briefly, the Attending Veterinarian (Dr. (b)(6)) reports to the Assistant Vice President for Technological Research and Innovation, who reports to the Vice President for Research (Dr. (b)(6)), who in turn reports to the President of the University. (b)(6) serves as the Chief Executive Officer of the University. (b)(6) has designated Dr. (b)(6) as the Institutional Official (IO). The IACUC reports directly to Dr. (b)(6) in his role as Assistant Vice President for Research Initiatives and Compliance. Both the Attending Veterinarian and the IACUC Chair have the authority to report directly to the IO if necessary.

The Center for Laboratory Animal Medicine is divided into four divisions: the Animal Husbandry Division (AHD), the Veterinary Medicine Division (VMD), the Veterinary Surgery Division (VSD), and the Administration Division. The LAM staff includes four military veterinarians, seven U.S. Army Animal Care Technicians (68T's), four U.S. Navy Surgical Technologists, and a civilian professional and technical staff of 18 individuals. The attached organizational chart for the ACUP (Appendix 4) provides the names and titles of supervisory personnel and the names of animal care personnel under each supervisor.

#### Supervisory Personnel

(b)(6) PhD Vice President for Research  
(b)(6) PhD, Assistant Vice President for Technological Research and Innovation  
(b)(6) MD, PhD, Assistant Vice President for Research Initiatives and Compliance

#### Compliance

(b)(6) DVM, MPH, Director, LAM, Attending Veterinarian  
(b)(6) DVM, MPH, Deputy Director, LAM  
(b)(6) DVM, MPH, Chief, Veterinary Surgery Division  
(b)(6) DVM, MPH, Chief, Veterinary Medicine Division  
(b)(6) LAT, Non-Commissioned Officer in Charge (NCOIC), LAM  
(b)(6) BS, MBA, LATG, Resource and Operations Manager  
(b)(6) LAT, Animal Husbandry Supervisor

- E. Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

The University representatives who will participate in the site visit are as follows:

(b)(6) DDS, MD, President, USUHS, CEO  
(b)(6) PhD, Vice President for Research, USUHS, Institutional Official  
(b)(6) DDS, PhD, Assistant Vice President for Technological Research and Innovation

(b)(6)	MD, PhD, Assistant Vice President for Research Initiatives and Compliance
(b)(6)	PhD, Chairperson, IACUC
(b)(6)	DVM, MPH, Director, LAM, Attending Veterinarian
(b)(6)	DVM, MPH, Deputy Director, LAM
(b)(6)	LAT, Non-Commissioned Officer in Charge (NCOIC), LAM
(b)(6)	VM, MPH, Chief, Veterinary Medicine Division, LAM
	COIC, Veterinary Medicine Division, LAM
	M, MPH, Chief, Veterinary Surgery Division, LAM
	S, MBA, LATG, Operations and Resource Manager, LAM
	LAT, Chief, Animal Husbandry Division, LAM
	IA, IACUC Administrator
	Director, Environmental Health and Safety (EHOS)
	S, University Safety Officer
	Occupational Health Nurse, Chief, Occupational Medicine

- F. Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

The University's research and teaching programs that use animals involve all disciplines of biomedical and behavioral sciences that are required to meet the educational objectives. The USUHS has 66 principal investigators participating in 159 research and 5 training protocols using animal models. The requested "Animal Usage" forms are included in Appendix 5.

- G. Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

The USUHS animal research program receives funding from many sources. The primary source of funding is grants from agencies within the Department of Health and Human Services. Other funding sources include the USUHS Intramural Program, the Department of Defense, and other non-federal agencies.

- H. List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.  
*Note:* Questions regarding this section should be forwarded to the AAALAC Office.

The Center for Neuroscience and Regenerative Medicine (CNRM) is a federal medical research program with collaborative interactions between the U.S. Department of Defense and the National Institutes of Health, and Walter Reed National Military Medical Center.

Congress established CNRM to bring together the expertise of physicians and scientists at these collaborating institutions in the National Capital Area to develop innovative approaches to brain injury diagnosis and recovery. The animal research is conducted at USUHS, Walter Reed Army Institute of Research, and NIH with many collaborative studies conducted with IACUC approved protocols in each collaborating institution. USUHS has a core behavioral and rodent surgery/procedure facility located in (b)(2) and (b)(2) areas that is separate from the LAM central animal facility. The space comprises 2,356 sq. ft. of procedure, surgery, and mouse behavioral testing dedicated to the study of traumatic brain injury (TBI). The CNRM has six different programs: (1) Diagnostics and Imaging – Advancing structural, metabolic, and functional brain imaging for TBI diagnosis, (2) Biomarkers – Identifying molecular and physiological indicators for TBI diagnosis, (3) Neuroprotection and Models – Preventing tissue damage and cell death after TBI, (4) Neuroregeneration – Developing strategies to enhance CNS repair after TBI, (5) Neuroplasticity – Optimizing neural circuitry for recovery of function after TBI, and (6) Rehabilitation and Evaluation – Assessing and improving functional capacity after TBI. The Translational Imaging Facility contains (room (b)(2) and room (b)(2) (b)(4) Positron Emission Tomography (PET) Scanner – live animal imaging for neuroscience and other applications (b)(4) Computed Tomography (CT) Scanner – live animal imaging for neuroscience and other applications; and (b)(4) (b)(4) Magnetic Resonance Imaging (MRI) – live animal imaging for neuroscience and other applications.

CNRM receives separate funding and has an organizational structure outside that of LAM.

- I. Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

N/A

- J. Note other relevant background that will assist reviewers of this report.

The integration of the adjacent Armed Forces Radiobiology Research Institute (AFRRI) as a component of the University has resulted in many administrative and functional area realignments. At this time, both facilities maintain separate animal care and use programs, PHS assurances, and AAALAC accreditations.



## Section 2. Description

### I. Animal Care and Use Program

#### A. Program Management

##### 1. Program Management Responsibility [Guide, pp. 13-15]

###### a. The Institutional Official [Guide pp. 13-14]

Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The President of the University (b)(6) has designated Dr. (b)(6) (b)(6) as the Institutional Official (IO). The needs of the USUHS animal care and use program are clearly and regularly communicated to Dr. (b)(6) by the Assistant Vice President for Technology, Research and Innovation, Dr. (b)(6) who meets with (b)(6) the Attending Veterinarian, via face-to-face weekly meetings and through electronic communication as necessary. (b)(6) reports directly to Dr. (b)(6) however (b)(6) may report directly to Dr. (b)(6) as needed. Dr. (b)(6) also supervises Dr. (b)(6) Assistant Vice President for Regulatory Compliance, who oversees the IACUC administrative staff and is regularly kept abreast of animal program issues.

Dr. (b)(6) IACUC Chair, communicates program needs to Dr. (b)(6) and Dr. (b)(6) through electronic, telephonic, and face-to-face communication; semiannual facility inspections and program review reports signed by a majority of the IACUC members; and IACUC meeting minutes.

###### b. Role of the Attending Veterinarian [Guide, p. 14]

- i. Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:

- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

LAM operates under the direct supervision of the Director, who reports to the IO through the Assistant Vice President for Technology, Research and Innovation. LAM has four veterinarians who are available to provide appropriate veterinary care. All veterinarians are employed full-time by the USUHS. The following list provides information on the University's laboratory animal veterinarians:

(b)(6)

DVM, MPH, DACVPM, DACLAM, Director, LAM.

Attending Veterinarian.

Responsibilities are as follows:

- Provide leadership and direction to LAM
- Serve as AV on the USUHS IACUC
- Directs the operation of the humane care and use of laboratory animal species housed within the animal facility
- Make recommendations to ensure that the LAM and USUHS's animal care and use program are in compliance with the Animal Welfare Regulations, PHS Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and Department of Defense (DOD) regulations
- Provide veterinary care for all animal species in LAM
- Provide expertise in the use of sedatives, analgesics, or anesthetics
- Implement policies to establish health surveillance and monitoring programs, including the use of sentinel animals
- Oversee training for laboratory animal technicians, students, and research personnel in proper techniques for the care and use of laboratory animals
- Provide expertise to research personnel on issues related to use of appropriate animal models
- Provide budgetary development and oversight of the LAM
- Oversee operation of a cost accounting and charge back program for LAM
- Oversee facility management and husbandry operations
- Oversee Lab Animal Medicine Residents training program
- Dedicates at least 90% of his time to supporting the animal care & use program (ACUP)

(b)(6)

DVM, MPH, Deputy Director, LAM

Responsibilities are as follows:

- Serve as the alternate AV on the USUHS IACUC
- Assist the Director with operation of the humane care and use of laboratory animal species housed within the animal facility
- Makes recommendations to ensure that the LAM and USUHS's animal care and use program are in compliance with the Animal Welfare Regulations, PHS Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and Department of Defense (DOD) regulations
- Provide veterinary care for all animal species in LAM
- Provide expertise in the use of sedatives, analgesics, or anesthetics

- Oversee veterinary medical and surgical care and support to include disease surveillance and preventive medicine
- Provide training for laboratory animal technicians, students, and research personnel in proper techniques for the care and use of laboratory animals
- Provide expertise to research personnel on issues related to use of appropriate animal models
- Assist Director with facility management and husbandry operations
- Assist Director with residency program
- Dedicates at least 90% of her time to supporting the (ACUP)

(b)(6) DVM, MPH, Chief, Veterinary Medicine Division (VMD)

Responsibilities are as follows:

- Provide veterinary care for all animal species in LAM
- Provide expertise in the use of sedatives, analgesics, or anesthetics
- Oversee veterinary medical and surgical care and support to include disease surveillance and preventive medicine
- Provide training for laboratory animal technicians, students, and research personnel in proper techniques for the care and use of laboratory animals
- Provide expertise to research personnel on issues related to use of appropriate animal models
- Dedicates 80% of her time to supporting the (ACUP)

(b)(6) DVM, MPH, ACVPM, Chief, Veterinary Surgery Division (VSD)

Responsibilities are as follows:

- Provide veterinary care for all animal species in LAM
- Provide expertise in the use of sedatives, analgesics, or anesthetics
- Oversee veterinary medical and surgical care and support to include disease surveillance and preventive medicine
- Provide training for laboratory animal technicians, students, and research personnel in proper techniques for the care and use of laboratory animals
- Provide expertise to research personnel on issues related to use of appropriate animal models
- Dedicates 80% of her time to supporting the (ACUP)

- ii. List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

The following personnel are LAM technicians that provide direct medical and surgical care in support of both clinical needs and research projects:

**VSD**

(b)(6)

Surgical Tech  
Surgical Tech  
Surgical Tech  
Surgical Tech

**VMD**

(b)(6)

Veterinary Tech  
Veterinary Tech  
Veterinary Tech  
Veterinary Tech  
Veterinary Tech  
Veterinary Tech

(b)(6)

Chief, AHD, ALAT has overall responsibility for the daily provision of animal husbandry and supervises the following animal caretakers:

(b)(6)

**c. Interinstitutional Collaborations [Guide, p. 15]**

Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

N/A

**2. Personnel Management**

**a. Training, Education, and Continuing Educational Opportunities**

Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.

**Note:** Do not include details about the training program, which should be described in the following sections.

The IACUC oversees and evaluates training and education of all personnel involved in the ACUP. As part of the protocol review process principal investigators must provide qualifications and experience related to the requested species for all personnel that will handle animals. This information is presented in the protocol for IACUC review and approval. Training, qualifications, and experience of research personnel are reviewed by the IACUC during each protocol's annual review if additional personnel are requested at that time. The IACUC has established training requirements for investigators prior to the initiation of animal work. All investigators must complete the (b)(2) offered by I AM personnel and the (b)(4) (b)(2)

(b)(2) Documentation of completion is provided to the IACUC office. Investigators proposing to work with rats or mice are required to (b)(2) (b)(2) before commencing studies unless they can present evidence of prior training at another AAALAC-accredited facility or evidence of substantial experimental experience. LAM will provide and document species- or protocol-specific training as needed or requested. New IACUC members are required to complete the (b)(4) (b)(4)

(b)(2) IACUC members must renew their training by retaking the (b)(2); (b)(4) Completion certificates are (b)(2)

(b)(2) IACUC members are encouraged to (b)(2)

(b)(2) and/or related training opportunities, as funding allows. (b)(2)

(b)(2)

**i. Veterinary and Other Professional Staff [Guide, pp. 15-16]**

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.

**Note:** Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

<b>Veterinarians</b>	
(b)(6)	DVM, MPH, DACLAM, DACVPM
-Completed Laboratory Animal Medicine Residency	
- 16+ years lab animal experience	
-Attends National AALAS Meeting	
(b)(6)	DVM, MPH, DACVPM

-Completed Laboratory Animal Medicine Residency

-4 years lab animal experience

- Attends APV, AWIC, POLA/CLASS

(b)(6) DVM, MPH, DACVPM

-3rd year Laboratory Animal Medicine Resident

- 3 years lab animal experience

- Attends APV, AWIC, POLA/CLASS, AALAS

(b)(6) DVM, MPH

-2nd year Laboratory Animal Medicine Resident

- 2 years lab animal experience

- Attends APV, AWIC, POLA/CLASS

#### Technicians

(b)(6) LAT, Veterinary Tech

- 16 years of technician experience

-Attends National AALAS and NCAB AALAS meetings

#### VSD

(b)(6) Surgical Tech

- 2 years of lab animal experience

(b)(6) Surgical Tech

- 3 years of lab animal experience

(b)(6) Surgical Tech

- 2 years of lab animal experience

(b)(6) Surgical Tech

- 0 years of lab animal experience

-All may attend NCAB AALAS meetings

#### VMD

(b)(6) Veterinary Tech

- 11 years of technician experience

-Attends NCAB AALAS meetings

(b)(6) Veterinary Tech,

- 5 years of technician experience

-Attends NCAB AALAS meetings

(b)(6) Veterinary Tech

-3 years of technician experience

-Attends NCAB AALAS meetings

(b)(6) Veterinary Tech

- 3 year of technician experience

-May attend NCAB AALAS meetings

(b)(6)

- 2 years of technician experience

-May attend NCAB AALAS meetings

(b)(6) Veterinary Tech

-1 year of technician experience

(b)(6) BS, CVA, ALAT, Veterinary Tech

- 22 years technician experience
- May attend NCAB AALAS meetings

All technicians are United States Army Veterinary Care Technicians (with exception of (b)(6) trained in basic care and treatment of animals with additional training in laboratory animals or United States Navy Hospital Corpsmen trained as human surgical technologists. They complete a rigorous six month course that prepares them to perform with limited supervision. The Navy Corpsmen have received additional training through LAM in animal care and handling. All technical staff are afforded local continuing education opportunities such as NCAB AALAS meetings/seminar, workshops, and AALAS webinars.

## ii. Animal Care Personnel [Guide, p. 16]

1) Indicate the number of animal care personnel.

12

2) Summarize their training, certification level and type, experience, and continuing education opportunities provided.

Note: If preferred, this information may be provided in a Table or additional Appendix.

All animal husbandry personnel undergo on-the-job- training on departmental SOPs, policies, and practices under the supervision of the Chief, Animal Husbandry. All animal care staff must also participate in institutional required courses in occupational health, hazardous agents, and safety. Animal husbandry personnel have the following amount of husbandry and animal handling experience:

(b)(6) LAT, 25 years  
(b)(6) BS, LATG, 6 years  
(b)(6) ALAT, 20 years  
(b)(6) 30 years  
(b)(6) 31 years, LAT  
(b)(6) 32 years  
(b)(6) 14 years  
(b)(6) 5 years  
(b)(6) 28 years  
(b)(6) 30 years  
(b)(6) BA, 6 years  
(b)(6) 6 years

Personnel may be able to attend local (b)(2) and events as funding permits.

iii. The Research Team [Guide, pp. 16-17; 115-116; 122; 124]

- 1) Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

The IACUC oversees and evaluates training and education of all personnel involved in the ACUP. As part of the protocol review process principal investigators must provide qualifications and experience related to the requested species for all personnel that will handle animals. This information is presented in the protocol for IACUC review and approval. The IACUC has established training requirements for investigators prior to the initiation of animal work. All new investigators must complete the (b)(2); (b)(4) (b)(2) course. Certificates from the online courses are (b)(2) (b)(2) All investigators must complete the (b)(2) (b)(2) Investigators proposing to work with mice or rats are also (b)(2) presented by LAM unless prior experience or training can be demonstrated to the IACUC. LAM can also provide species- or procedural-specific training on a case-by-case basis. Training, qualifications, and experience are reviewed annually by the IACUC during each protocol's annual review and during semi-annual program reviews.

- a) Briefly describe the content of any required training.

The Investigator Training Course includes a PowerPoint presentation to emphasize the important points in reference to the following topics: investigator responsibilities; ethics of research animal use; reporting of perceived animal welfare concerns; alternatives to animal use; animal rights/welfare groups; biosafety; appropriate animal handling and care; current laws and legislation; guidelines on research animal use; anesthesia, analgesia, and euthanasia; literature search sources and avoidance of duplicative research efforts; acceptable aseptic surgical methods and procedures; proper pre- and post-surgical care; the University's policy for laboratory animal care and use; IACUC policies; Environmental and Occupational Health, zoonoses, and allergens; and LAM points of contact.

- b) Describe the timing of training requirements relative to the commencement of work.

Personnel using animals at USUHS are (b)(2) (b)(2), (b)(4) prior to using



animals at the University. Attendance at (b)(2)  
(b)(2) prior to working with rodents. The (b)(2)  
(b)(2) (or as needed) to all  
new University research staff members.

c) Describe continuing education opportunities offered.

For those individuals requiring additional or specialized handling, care and procedure instruction, LAM staff and/or experienced University research staff members provide hands-on training on a one-to-one or small group basis. There is also an animal-user e-mail group by which information, new IACUC policies, and educational articles are provided to animal users throughout the University by the IACUC office. New animal users are added to the e-mail group whenever a new protocol is approved. Continuing education opportunities are provided to the research staff at the discretion of the PI and their respective department.

- 2) Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:
- who determines that personnel are qualified and trained for surgical procedures
  - the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

Prior to approval of research or training protocols requiring surgery, the Attending Veterinarian and the IACUC members review the credentials, experience, and training of all investigators that will be performing surgical procedures. The IACUC will make the final determination as to whether or not investigators possess sufficient training and experience for the requested procedure(s). If investigators do not have adequate experience or training in good surgical technique or experience with the species being used, they must attend training conducted by LAM veterinarians. A LAM veterinarian will assess when an individual has achieved a minimum level of competency with a surgical technique. If the principal investigator is determined by the IACUC to be proficient in performing the procedure, the PI may train their research staff. The PI is ultimately responsible for ensuring their research personnel are adequately trained. If specific hands-on training is provided by LAM, a LAM veterinarian will verify the investigator is capable of competently completing the procedure.

All surgical technicians are U.S. Navy Hospital Corpsmen and have received additional training in veterinary anesthesia from the LAM veterinary staff.

- 3) Describe the training and experience required to perform anesthesia. [Guide, p. 122]

As part of the (b)(2)  
(b)(2)  
(b)(2) Research personnel who will be working with rodents are (b)(2) provided by LAM before performing any procedures, unless previous experience or training can be demonstrated to the satisfaction of the IACUC. An experienced PI may provide additional training to their research staff. Anesthesia services may be provided by trained LAM veterinary and surgical technicians when requested. LAM will conduct individual or small group training for research personnel as needed.

- 4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [Guide, p. 124]

As part of the protocol review and approval process, the IACUC will determine if research protocol personnel have adequate training and experience to perform euthanasia. Research personnel who will be working with rodents are (b)(2) provided by LAM before performing any procedures. An experienced PI may provide additional training to their research staff. Euthanasia services may be provided by trained LAM veterinary and surgical technicians when requested. LAM will conduct individual or small group training for research personnel as needed.

**b. Occupational Health and Safety of Personnel** [Guide, pp. 17-23]

**i. Institutional Oversight** [Guide, pp. 17-19]

- 1) List the institutional entities (units, departments, personnel, etc.) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g., remote offices to which personnel must report).

The USUHS Center for Environmental Health and Occupational Safety (EHOS), IACUC, LAM, and the Institutional Biosafety Committee (IBC) are

involved in the planning, oversight, and operation for the occupational health and safety program as it relates to laboratory animal care and use.

Oversight of Occupational Health and Safety is led by the Assistant Vice President for Health and Safety, with primary oversight of five divisions: Radiation Safety; Industrial Hygiene and Environmental (IHE); Occupational Safety, Occupational Medicine; and Biosafety. The Assistant Vice President for Health and Safety is (b)(6)

The personnel key to the animal care and use program from the Center for Environmental Health and Occupational Safety are:

(b)(6) Director Environmental Health and Occupational Safety (EHS), Assistant Vice President for Safety and Environment (AVS); Captain, Medical Service Corps, U.S. Navy (Retired). BS, MBA, Radiation Safety/Health Officer (NRC Qualified) Officer,

(b)(6) Occupational Health Nurse Chief,  
Occupational Medicine  
Pharmacy Officer  
Employed at USUHS in this capacity for 24 years

(b)(6) University Safety Officer  
MS in Biotechnology (Univ of Tennessee); 10 years research experience in molecular biology/virology (NIH & USUHS); 8+ years as USU biosafety officer.

(b)(6) MS, MPH  
Deputy Director, EHOS  
Radiation Safety Officer  
July 2015-Present

(b)(6) University Safety Officer  
Safety and Occupational Health Program Manager Chief, Occupational Safety Division (OSD); Safety Manager: Uniform Services University of the Health Sciences (USUHS) 11/2014-Present

(b)(6)  
USAF / Bioenvironmental Engineering Craftsman  
Division Chief, IHE

- 2) Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties

and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [Guide, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

The USUHS EHOS conducts safety inspections of all areas of the University every annually to identify potential and existing hazards and to evaluate safe work practices. The inspections utilize a numeric scoring system or risk assessment codes to describe levels of risk; the higher the risk, the more urgent the required corrective action. All reports of safety inspections are routed to the area Supervisor and the Supervisor is given 30 days to reply with appropriate action plan for any deficiencies.

The EHOS office also screens all University employees. New employees are risk assessed by their supervisors using the Supervisor's Occupational Risk Assessment Form (Appendix 6). This form is completed by the employee's supervisor and provided to EHOS. Risk assessments are conducted jointly between the PI, IACUC, and EHOS during the protocol review process.

Hazards are also identified in the animal research protocol. Investigators submitting research protocols involving work with bio-hazardous agents are routed through EHOS and the IBC for approval, comment, revision or denial, as appropriate. The use of select agents and toxins is governed by the U.S. Center for Disease Control (CDC) Select Agent Program. No Select Agents are currently being used at the university.

Employees that are expected to receive 10% or more of the annual radiation limit are enrolled in the Radiation Safety Program and monitored for exposure. LAM does possess a C-arm fluoroscope but it is rarely used by researchers and has not been used for the past several years by LAM for diagnostic purposes. It has occasionally been used by one specific PI to verify placement of electrodes in the heart during swine surgeries. LAM does not currently have any personnel enrolled in the Radiation Safety Program. Per the Radiation Safety Officer, dosimetry is not necessary for other employees if there is no routine use. LAM does possess lead aprons and gloves should use become necessary in the future. The Radiation Safety Officer will be notified if use becomes necessary.

The Naval Support Activity Bethesda fire department performs annual fire hazard inspections throughout the University as they assess hazards related to fire egress routes and flammable hazards.

3) Describe methods and frequency of reassessing work-related hazards.

As mentioned above, the USUHS EHOS conducts safety inspections of all areas of the University every annually to identify potential and existing hazards and to evaluate safe work practices. The inspections utilize a numeric scoring system or risk assessment codes to describe levels of risk; the higher the risk, the more urgent the required corrective action. All reports of safety inspections are routed to the area Supervisor and the Supervisor is given 30 days to reply with appropriate action plan for any deficiencies.

Work-related hazards are additionally identified and addressed as situations involving protocols or day-to-day operations. SOPs addressing such situations and/or operations are modified as needed.

4) Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [Guide, pp. 18-19]

Exposure to hazards or work place injuries must be reported to the first line supervisor. Any person who is injured or suffers exposure to a hazardous material must report the EHOS Occupational Health Nurse/Physician during regular business hours or the National Walter Reed Military Medical Center Emergency Room during evenings, holidays, or weekends. Contractors are encouraged to seek care from their medical provider or contracted care physician. Notification of the Occupational Health Nurse/Physician will trigger an incident investigation by EHOS Occupational Safety Division to determine the root cause and corrective actions necessary to prevent recurrence. (b)(2)

(b)(2)

(b)(2)

The area Supervisor and Safety Office will conduct follow up investigations into the incident.

Employees are encouraged to report near misses to their supervisor and EHOS Occupational Safety Division so that potentially hazardous situations can be identified and corrected.

ii. **Standard Working Conditions and Baseline Precautions**

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in **subsection iii** below.

1) **Medical Evaluation and Preventive Medicine for Personnel** [Guide, pp. 22-23] *Note:* Include blank forms used for individual health assessment as

## Appendix 6.

- a) Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are **not** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

There are no mandatory criteria for entrance into the medical surveillance program for USUHS workers exposed to animals. The directive of the medical surveillance program and subsequent personal medical evaluations is based on the risk based analysis as described in the job description as outlined by the Department. All individuals requesting access to LAM<sup>(b)(2)</sup>

<sup>(b)(2)</sup>

The program is designed for all USUHS workers with occupational exposure to animals including: a) the direct care of animals or their living areas, or b) the direct contact with animals (live or sacrificed), their viable tissues, body fluids, or wastes. Animal workers are placed into three risk categories based upon the type of animals handled as noted below:

Risk Category 1: rodents, rabbits, aquatics

Risk Category 2: cats, dogs, livestock, ferrets

Risk Category 3: nonhuman primates

Most non-Center for Laboratory Animal Medicine employees with exposure to animals will complete the medical history described above, and a determination will be made if additional study, including a physical examination, is indicated. This includes facilities and maintenance workers with intermittent exposure within the animal housing areas.

- b) Describe provisions for allowing an individual to decline participation in all or parts of the medical evaluation and preventive medicine programs (if applicable). Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.

Individuals are counseled upon their arrival to USUHS on the medical evaluation and preventative medicine program. Each individual can choose

to participate in the program or not, only if such a requirement is not mandated as part of their job description. In addition, those individuals requesting access to LAM must have a valid Occupational Health Screen, with annual renewal, prior to access being granted. Individuals who decline participation in the program must have their Supervisor's approval to continue working as it is ultimately the Department's Supervisor who can limit the work conducted by an individual based on the completion of any portion of the Occupational Health evaluation and preventative medicine program.

c) Describe provisions for assuring confidentiality of medical information.

Civilian Medical records

(b)(2)

(b)(2)

(b)(2)

d) Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

For visitors and contract employees who require clearance to enter LAM, occupational health services must be arranged through their agency or other healthcare provider, and documented on the "Supervisor's Risk Assessment form". The form is submitted to Occupational Medicine for issuance of a Medical Surveillance Certification card. For durations of exposure for a day or less, Visitors and contract employees are notified in writing of the potential risk for exposure to animal allergens, animal waste, and other potential hazards upon entering into LAM. All those with durations longer than a day are required to complete the "Supervisor's Risk Assessment Form."

e) Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

(b)(2)

Military LAM workers may receive either a physical examination or medical surveillance screening using the Animal Exposure Surveillance Medical History questionnaire. Contract workers are required to follow the requirement of their contract. Non-LAM employees with exposure to animals are also screened annually using the medical history form described above, and a determination will be made if additional study, including a physical examination, is indicated.

USUHS animal handlers are offered immunizations known to be safe and effective. Risk assessment is based on input from the animal handler, their supervisors, the professional veterinarian staff, and the EHOS safety professionals. All animal handlers are offered updated Tdap, and Hepatitis B immunizations. Other possible vaccinations include yellow fever, rabies vaccine, polio vaccine, VEE vaccine, and others are offered with need based upon risk assessment performed during initial Occupational Health screening assessment.

Rabies vaccine is offered to workers handling animals potentially infected with rabies and to those who capture or destroy wild animals on the University campus. Periodic serologic monitoring is performed on this group of workers. All USUHS workers (military, contract or DoD civilian) working directly with experimentally infected animals with viruses of the Rhabdoviridae family are required to receive counseling on receiving the Rabies vaccine. Any individual refusing to receive the Rabies vaccine will be reviewed by their Supervisor for need-based risk of exposure to the Rabies and/or Rabies related agent in relation to the procedures of their protocol. Serological testing for toxoplasmosis is obtained for immuno-compromised animal handlers and women who are capable of childbearing who anticipate exposure to cats or their feces. If titers are interpreted as not protective we counsel the animal handler regarding potential risks to herself and her fetus. Job reassignments may be necessary for these animal handlers. As noted above, University animal handlers are not anticipated to have occupational exposure to cats or their feces.

- f) Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

WRNNMC ER is used for emergency and after hours care for DoD civilians and military personnel (b)(4) contracts with



(b)(6)  
an Occupational Health Physician (Dr (b)(6) in Gaithersburg) and (b)(6)  
(b)(6) for after hour and emergency care. (b)(4)  
employees who require medical care are directed to report to the entity as  
listed in their contract. Currently (b)(4) employees will report  
to (b)(4) for medical care.

**2) Personnel Training Regarding Occupational Health and Safety**  
[Guide, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

**Note:** Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

All University employees, to include administrative personnel, are required to take an online safety training course for New Employees.

EHS offers training for all laboratory personnel covering Basic OSHA Rights, General Laboratory Safety, Hazard Communication, and Regulated Medical Waste (Biowaste), as well as training if necessary covering Bloodborne Pathogens, Liquid Nitrogen, Formaldehyde Handling, Radiation, and Controlled Substances. All laboratory and animal facility employees are (b)(2)

(b)(2)  
(b)(2) for all personnel handling human blood or tissues.

The frequency of required EHOS training is as follows:

(b)(2)

The following EHOS trainings are reserved for individuals that have been identified by their immediate Supervisor as requiring having the training to be able to function for the capacity within their lab. Not every individual at USUHS will have the following trainings with the required frequencies:

(b)(2)

Principle Investigators oversee specific biological and chemical hazards that will be used in their respective laboratories. The IACUC is responsible for ensuring through the Primary Investigator with their area Supervisors that all required training is completed with copies of training certificates available on request.

Additionally all personnel identified to be involved with an animal protocol are

(b)(2)

(b)(2)

The course covers types and sources of animal allergen exposure within LAM, the risks of handling sharps with proper disposal methods, brief description of the Occupational Health program and the resources provided, zoonotic diseases, personal hygiene and PPE. The PI training is provided by a LAM veterinarian on a monthly basis.

Completion of all training is required before the IACUC will grant approval for anyone to work with animals.

LAM veterinarians and technicians conduct species-specific workshops for most rodent species used at USUHS. These courses stress safe animal handling practices as a means of preventing occupational exposure. LAM personnel also receive continuing on-the-job training in husbandry, animal handling, and safety. EHOS provides a variety of pamphlets and literature outside the Occupational Health Nurse's office regarding various occupational health and safety issues, which are available to all University employees.

### 3) Personal Hygiene [Guide, p. 20; Ag Guide pp. 4-5]

- a) List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Proper measures are taken to reduce the potential for transmission of diseases from laboratory animals to personnel. Care is taken to protect staff from contact with hazardous agents and animal allergens. All staff

members are expected to maintain a high standard of personal cleanliness and to wear the required protective clothing.

Scrubs and lab coats are provided as work uniforms. Rubber boots are worn in the cage wash area and swine housing areas. Clean scrubs are provided daily and are laundered by a contract laundry service. Caretakers are not permitted to leave the central animal facility in their work clothes unless to perform animal care duties (e.g. receiving animals, removing trash, cleaning satellite rooms, etc.).

Personal protective equipment routinely provided to all USUHS employees within LAM is gloves, hair net, shoe covers, and mask. All USUHS personnel have access to cloth lab coats with unlimited number of launderings available. Tyvek suits and/or disposable lab coats are available within LAM for entry into specific rooms (BSL-2, Barrier, Quarantine, or Isolation) or for USUHS personnel requesting more personal protection.

Surgical scrubs, Tyvek suits and/or lab coats are required for entry into animal rooms. Surgical type face masks are available and are required for entry into swine, ferret, rabbit, opossum and all BSL-2 rooms. Surgical face masks are optional for entry into BSL-1 rodent rooms. Dust/mist respirators (N95 & N100) may be worn voluntarily in place of the surgical type face mask. Latex or nitrile exam gloves are worn by anyone working with the animals, cages, or animal wastes. Additional protective equipment may be required in ABSL-2 rooms; this varies with the risk factors associated with the agent and the protocol. Specific entry requirements and agents present are listed on the biohazard sign posted on the animal room door.

Ear protection is required in high noise areas (cage wash and swine housing areas) and earplugs are available for this purpose.

Eye protection is available and is required in all areas where there is a risk of a splash exposure. The University does not house or use non-human primates.

**b) Describe arrangements for laundering work clothing.**

All lab coats and scrub tops are laundered through a	(b)(2); (b)(4)
(b)(2), (b)(4)	All items are sent out for laundering on a twice weekly basis per contract. All University staff can request a clean lab coat and scrubs through the university laundering service.

- c) Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

As directed by the BMBL, a hand washing sink is located in all animal rooms within the LAM core. Each sink is stocked with soap and paper towels for hand washing. Satellite animal housing rooms do not have a sink located within those rooms. Satellite animal housing rooms instead have hand sanitizer located immediately outside of the door for use following exit of these rooms.

Work clothes (scrubs and lab coats) are not allowed to be worn outside of the University facility. Scrubs and lab coats are not allowed to be worn outside of laboratory procedure or LAM space. Per University rules, lab coats and scrubs are not allowed to be worn in University common areas. USUHS research personnel, excluding LAM staff, are required to change lab coats between BSL-2 rooms and any other animal housing room.

There are two sets of changing rooms and showers located within the central animal facility.

- d) Describe policies regarding eating, drinking, and smoking in animal facilities.

Eating and drinking are not permitted in any animal area or laboratory space. Eating and drinking are only allowed in a designated break room, office space or administrative areas. All food for human consumption is stored outside of animal housing rooms in designated refrigerators or office space. Smoking is prohibited near or within the animal facility.

#### 4) Standard Personnel Protection [Guide, pp. 21-22]

- a) Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

Hazard control and prevention follows the hierarchy of controls with engineering controls taking precedence over administrative controls followed by personal protective equipment (PPE). Engineering controls include facility design such as once-through air handling system with animal rooms at negative pressure relative to corridors and the use of biosafety cabinets, chemical fume hoods, and laminar flow work stations. Administrative controls comprise the following; SOPs for PPE

requirements and working in the animal facility, a chemical hygiene plan, radiation safety program, safety policies, and training requirements. PPE is readily available throughout the animal facility. Only specific-pathogen free animals are purchased from reputable vendors to decrease the chance of exposure to zoonoses.

The use of hazardous regulated chemicals as well as biological agents, controlled substances, select agents, and radioactive materials must have prior approval from EHOS and additionally must be approved in the purchasing system by authorized EHOS personnel. As per the university's Chemical Hygiene Plan, chemicals used within LAM are identified and accompanying Material Safety Data Sheets (MSDS) are available.

- b) Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

The primary source of allergens are animal saliva, urinary proteins, hair, or dust from bedding and/or food.

The pre-placement evaluations offered through the Occupational medicine branch, EHOS has focused on regular monitoring to detect early symptoms and stages of sensitization. These evaluations have consisted of a detailed occupational history, personal medical history, prior symptoms of allergies, history of exposure to animals, and a history of atopy in the individual or family. The goal is to identify those individuals with pre-existing medical conditions that may make them more susceptible to developing allergies. Based on this initial assessment, more advanced study may be indicated and include physical examination, skin-prick testing (dermatology referral), immunoassay (RAST) testing, and pulmonary function testing.

Prevention programs are directed at minimizing exposure to animal urinary or salivary proteins by reducing, to the extent feasible, the dust in animal holding areas. Contact with animals is limited by reducing hours of exposure and/or by use of appropriate barriers. Maximum use is made of biological cabinets, special cages with filtering devices or special exhaust systems and appropriate personal protective equipment.

- c) Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

Zoonotic disease associated with rodent and rabbit research has been infrequent; concerns include lymphocytic choriomeningitis, tapeworm, and ringworm. Swine and ferrets are utilized at USUHS and serve as a potential respiratory zoonosis source. Proper handling of animals (including use of biosafety cabinets, when applicable) and appropriate wear of personal protective equipment is stressed as the most important way to prevent exposures.

- d) Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

Commonly employed protective equipment includes masks, gloves, scrubs, lab coats, and shoe covers. These items are regularly used and replenished throughout the animal facility.

e) Respiratory Protection

- i) Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

The use of a N95 mask is required, as indicated by LAM SOPs, during any cage changes by LAM personnel that are not able to be performed within a Laminar flow hood. N95 mask is also required when a functional bedding dump station is not available. A 5400 series full faced personal respiratory is also required for LAM personnel during the use of formaldehyde and/or formalin when such chemical agent is being transferred from the holding container to smaller necropsy jars.

- ii) Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

All personnel that require the use of either N95 mask or personal respirator are initially fit-tested and checked annually by Industrial Hygiene. All training in the proper use and maintenance of respiratory protective equipment is provided by Industrial Hygiene at the time of fit-testing.

- iii) Describe how such respiratory protective equipment is selected and its function periodically assessed.

Respiratory protective equipment is selected based on the risk assessment for the individual task using the most recent literature. The 5400 series personal respirators are fit-tested and functionally checked annually by Industrial Hygiene. The cartridges used within the 5400

series are replaced as indicated by the manufacture for durational hours of use.

f) Heavy Equipment and Motorized Vehicles

- i) Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.

*Note:* Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

Cage-processing equipment:

(b)(4) Tunnel Washer with bedding dispensing unit, room (b)(2)  
(b)(4) Cabinet Washer (2), room (b)(2)  
(b)(4) Feeder Bottle Filling Station, room (b)(2)  
(b)(4) Feeder Bottle Filling Station, room (b)(2)  
(b)(4) Steam Autoclave, room (b)(2)  
(b)(4) Sterilizer, room (b)(2)  
(b)(4) Autoclave, room (b)(2)  
(b)(4) Sterilizer, (2) room (b)(2)  
(b)(4) Waste Conveyor System, room (b)(2)

(b)(4) Rack washer 1

Emergency "off" button on the side of each door with a red sign; labeled push here to exit inside of each door, de-energizing cord on both sides, instructional signage pull cable to stop  
Each side has a door window and a light inside. Electrical panel shut off.

(b)(2) Rack washer 2

Emergency "off" button on the side of each door with a red sign; labeled push here to exit inside of each door, de-energizing cord on both sides, instructional signage pull cable to stop  
Each side has a door window and a light inside. Electrical panel shut off.

(b)(2) Tunnel washer

Emergency "off" button; instructional signage. Signs thou out the machine; danger hot, do not open when machine is operating, high voltage, pinch point hazards, danger hot and hot. Has photo eye sensors for motion

(b)(2)

Dirty Bedding chain removal system

Emergency "off" button and signage. touch screen notify when dumpster is gone. Electrical panel shut off. Arc flashing shock hazards loose screws and parts

LAM personnel receive on-the-job-training to properly and safely execute their daily duties. All personnel review and receive training on job-related SOPs. Animal Caretakers are issued steel-toed safety shoes. MSDS information is posted and available for employee use. Protective exam gloves, face shields, goggles, heat-resistant gloves, and aprons are available. Rubber boots are provided for use in wet areas. Hearing protection is required and made available for areas or tasks deemed a noise hazard by EHOS personnel. Areas of risk are clearly marked outside the risk area and posted with the required PPE. Wet floor and danger signs are used during hall mopping and facilities work. A barrel assist lift is used with 30-gal drums. Training on specific work place hazards and safe work practices (e.g. proper lifting technique) helps to familiarize personnel with potential risks and effective mitigation strategies. To minimize animal bites and scratches, personnel are trained to properly handle and restrain animals. Individuals are instructed to handle and properly dispose of sharp items (e.g. broken glass, syringes, needles, and scalpel blades). All compressed gas cylinders are equipped with appropriate regulators and are secured in place with straps or chains or contained in racks.

Staff working in the cage wash areas are required to read and understand SOPs and training related to those areas to include emergency egress from the washers. Cage washers are equipped with signage and mechanisms for emergency egress. These mechanisms consist of a door release mechanism and a power stoppage mechanism. As a safety precaution, individuals are only allowed to operate the equipment when others are working in the area. Appropriate PPE must be worn when handling chemicals, handling hot caging, and removing items from the autoclave.

- ii) List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

N/A



- iii) If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

LAM has a dedicated van that can be signed out from the motor pool and is used exclusively for animal transportation. The van has been customized for animal transport. The driver's compartment is separated from the animal compartment by a panel to protect against exposure to allergens or zoonoses. The animal compartment has separate heating and cooling to regulate the temperature. A stainless steel cage has been built into the animal compartment for transporting larger animals. The animal compartment is designed for easy sanitation and is cleaned before and after use. The LAM van is inspected at least semi-annually by the IACUC.

- g) Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

Inhalant anesthetic gas used in the CAF is scavenged through the use of the in-house vacuum system or through use of an electric scavenging pump and/or a charcoal canister where in-house vacuum is not available. Charcoal canisters are weighed before initial use and then weighed before each subsequent use. The weight is recorded on the side of the canister each time they are weighed, along with the date. Charcoal canisters may be monitored by either time used (maximum 12 hours) or by weight increase (maximum of 50 grams).

In University laboratories, volatile anesthetics are scavenged by one of three methods: the procedure is performed in a certified fume hood; scavenging using the in-house vacuum system or a vacuum pump that delivers to the building exhaust; or passive scavenging using charcoal canisters as described above.

### iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

- 1) List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

- a) Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

List of all agents current and previously used at USUHS. Agents bolded are currently in the facility:

**Escherichia coli (non-pathogenic)– BSL -1**  
Litomosoides sigmodontis - BSL 1  
**Ornithonyssus bacoti (Tropical Rat Mite)– BSL 1**  
**Enterohemorrhagic Escherichia coli - BSL 2**  
**Uropathogenic Escherichia coli - BSL 2**  
**Shiga Toxin-producing Escherichia coli - BSL 2**  
**Neisseria gonorrhoeae - BSL 2**  
Helicobacter pylori - BSL 2  
Bacillus anthracis Sterne- BSL 2  
Bacillus cereus - BSL 2  
GIPZ lentiviral shRNA mir – BSL 2  
Leishmania chagsi – BSL 2  
Streptococcus pneumonia – BSL 2  
Staphylococcal enterotoxin B - BSL 2  
Pseudomonas aeruginosa – BSL 2  
Salmonella typhimurium – BSL 2  
Salmonella enteritidis – BSL  
**Zika virus, BSL-2**  
**Enterococcus faecalis - BSL-2**  
**Methicillin-resistant Staphylococcus aureus – BSL-2**  
**Epstein-Barr Virus – BSL-2**  
**Chikungunya virus (181/25) – BSL-2**  
**Influenza virus – BSL-2**  
**Lyssa Virus – BLS-2**  
**Respiratory Syncytial Virus - BSL-2**  
**Malaria - BLS-2**

- b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

Tamoxifen – Anti-neoplastic  
Cuprizone - Chelator  
Soman - Toxin  
Ricin – Toxin  
5-Fluorouracil – Radioactive Tracer  
Carbon Monoxide – Toxicant

Paraformaldehyde – Corrosive, Carcinogen  
Formaldehyde - Corrosive, Carcinogen  
Imatinib – Anti-neoplastic  
Bromodeoxyuridine (BrdU) – Mutagen  
Chlorodeoxyuridine - Mutagen

- c) Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

Cs137 Radiation  
Magnetic Resonance Imaging  
Fluoroscopy  
Acoustic Startle Chamber  
Controlled Cortical Impact TBI  
Lateral Fluid Percussion TBI  
High Intensity Focused Ultrasound TBI

- 2) **Experiment-Related Hazard Use** [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].

*Note:* Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

- a) Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

During the protocol review process, the LAM veterinarian, in conjunction with the institutional biosafety officer, evaluates the protocol for hazards as described in the protocol by the principle investigator. Depending on the hazard identified, the primary investigator may need to develop a laboratory specific SOP covering the steps the laboratory use with the identified hazards. Institutional Biosafety Committee (IBC) reviews all protocols and SOPs for handling infectious agents and/or procedures using recombinant DNA. All LAM personnel will follow procedures as outlined within LAM SOPs.

- b) Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

The USUHS has published instructions and letters on such topics as Chemical Safety, Biological and Infectious Material Safety, Radiation Safety, Waste Disposal, Animal Safety, etc. These policy letters describe levels of responsibilities and give detailed instructions on proper procedures to follow

when using hazardous materials. Every effort is made to conduct this research safely and to minimize hazard exposure whenever possible. MSDS are maintained on all hazardous products maintained in laboratories and in LAM. MSDS information is maintained and readily available to all personnel using hazardous materials. A complete description of the hazard and appropriate safety precautions must be included in the animal protocol and approved by the IACUC. Any questions the IACUC may have regarding the hazard are referred to the investigator or appropriate safety officer (biological, chemical, radiation) for comment.

- c) Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

Animal rooms containing BSL-2 agents are maintained under negative pressure. PPE worn in ABSL-2 rooms is disposed of as biohazardous waste prior to leaving the room. Caging is double-bagged and the outside of the bag disinfected with MB-10 prior to autoclaving the cages before sanitation through the cage washer. Carcasses are sealed in an autoclavable biohazard bags which are in plastic, biohazard containers. The containers are disinfected with MB-10 prior to transfer to (b)(2) for sterilization. Sticky mats or foot baths are used to prevent spread of contamination.

- d) Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

When a hazardous agent is identified during the protocol review process, additional medical evaluations and/or health screenings can be offered and/or required as determined by the Institutional Biosafety Officer in conjunction with the Occupational Health Nurse and LAM veterinarians based on the agent being used.

**3) Hazardous Agent Training for Personnel [Guide, p. 20]**

Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

The USUHS EHOS requires training in hazardous materials/hazard communication and laboratory safety. If a protocol involves hazardous agents in animals, the Primary Investigator is responsible for ensuring that all persons are properly trained. LAM veterinarians in conjunction with husbandry staff work with investigators to determine what special husbandry procedures are necessary and participates in training technicians and caretakers as needed. The Radiation Safety Officer ensures that personnel are appropriately trained before permission to work with radioisotopes is granted.

**4) Facilities, Equipment and Monitoring** [*Guide*, pp. 19-20]

- a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).

*Note:* If preferred, information may be provided in a Table or additional Appendix.

The following rooms use hazardous agents and are maintained as ABSL - 2 rooms. All animal rooms have a negative air pressure differential.

Room	(b)(2)	103 sq. ft.) – BSL-2 ; MRSA – Rat – Static Caging – Negative
airflow		
Room		103 sq. ft.) – BSL-2 : ABLV – Rat – Static Caging – Negative air
flow		
Room		219 sq. ft.) – BSL-2 – RSV, Influenza, Malaria, Chikungunya –
Mice		caging – Negative airflow
Room		220 sq. ft.) – BSL-2 - Neisseria gonorrhoeae – Mice – IVC
Caging		negative airflow
Room		230 sq. ft.) – BSL-2 – ABLV – Mice – Static caging – negative
airflow		
Room		297 sq. ft.) – BSL-2 - Enterococcus fecalis - Rabbits –
		conventional rabbit caging – negative airflow
(b)(2)		(207 sq. ft.) – BSL-2 - Escherichia coli (non-pathogenic),
		Enterohemorrhagic Escherichia coli, Uropathogenic Escherichia coli, Shiga
		Toxin-producing Escherichia coli – Mice – Static Caging – Negative airflow
(b)(2)		(212 sq. ft.) – BSL-1 - Ornithonyssus bacoti – Gerbils – Static Caging
		with a moat to prevent mite escape– Negative airflow
Room	(b)(2)	(529 sq. ft.) – BSL-2 – Zika virus – Ferrets – Conventional ferret
		caging – Negative airflow

**Biosafety Cabinets:**

Room	(b)(2)	– Sterigaurd II Baker Class A2
Room		– Sterigaurd II Baker Class A2
Room		– Baker Class II A2
Room		– Formscientific Class II A2
(b)(2)		– Allentown Class II A

Exhaust air from the BSL-2 rooms is not treated.

- b) Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard

containment.

Currently, animals under protocols utilizing hazards are not housed in rooms located outside of central animal facility oversight.

- c) Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

Biosafety cabinets, chemical fume hoods, bedding dump stations, downdraft tables are certified annually by a professional vendor. Anesthetic vaporizers are sent out to a professional vendor annually for maintenance and calibration. Proper working conditions of the cage and rack washers and autoclave units are maintained through annual maintenance or repairs via vendor contract. Opening of the cage washer door from within the unit is tested by AHD staff and the IACUC during semi-annual facility inspections

- d) Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

SOPs are in place for husbandry practices and room access including PPE requirements. Room doors are labeled with biohazard signage which indicates the organisms present and required safety precautions for entrance. Cages are changed within Biological Safety Cabinets. Caging is double-bagged and the outside of the bag disinfected with MB-10 prior to autoclaving the cages before sanitation through the cage washer.

- e) Incidental Animal Contact and Patient Areas

- i) List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

N/A

- ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

Animals are routinely removed from the LAM vivarium and transported to investigator laboratories for procedures and then may be returned. Animals are transported to/from the loading dock to the CAF through a common use corridor. Additionally, animals and caging are transported through common access corridors to rooms (b)(2) and

(b)(2) Animal transport utilizes only freight elevators and not passenger elevators. Animals are transported in their home cages and placed on carts or in dedicated transportation units. Animal caging or transportation units are covered to limit visualization of the animals and allergen exposure. The corridors are minimally populated with individuals not associated with the animal program. For animals residing in BSL-2 housing that require movement, those cages (rodents and ferrets) are double bagged with the tops loosely secured with the outside of each bag disinfected with MB-10 prior to any movement outside of animal housing room.

## B. Program Oversight

### 1. The Role of the IACUC/OB [Guide, pp. 24-40]

#### a. IACUC/OB Composition and Function [Guide, pp. 17; 24-25]

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7**.

##### i. Describe Committee membership appointment procedures.

Each IACUC member is appointed by the IO (b)(6) The IACUC Chair may recommend/nominate individuals for consideration by the IO.

##### ii. Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

The USUHS IACUC meets monthly.

##### iii. Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [Guide, p. 17]

New members are provided reference material to include the Guide for the Care and Use of Laboratory Animals, 8th ed and a new member's information packet.

(b)(2); (b)(4)

The following optional courses are (b)(2); (b)(5)  
(b)(2); (b)(5)  
(b)(2); (b)(5) IACUC members  
are encouraged to attend continuing education (CE) opportunities depending on  
availability and funding. Participation in CE opportunities has included attendance  
at PRIM&R IACUC Conference, IACUC 101/201, and SCAW Conference.  
Training is also conducted during regularly scheduled IACUC meetings.

**b. Protocol Review** [Guide, pp. 25-27]

A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

- i. Describe the process for reviewing and approving animal use. Include descriptions of how:
- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
  - protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
  - veterinary input is provided, and
  - the use of animals and experimental group sizes are justified.

*Note:* Make sure you address each of the items above.

All investigators are required to get a veterinary pre-review of their protocol prior to submission for IACUC review. The veterinary pre-review is intended to provide additional guidance to the PI regarding animal pain and distress issues, proper planning for the use of anesthetics, analgesics, and/or tranquilizing agents, surgical procedures and techniques, and proper methods of euthanasia. Additional administrative steps include verification by the appropriate department head of good scientific practice and merit and verification that the experimental design incorporates the appropriate statistical analysis or other applicable evaluative tools.

There are two potential review pathways after a protocol is submitted to the IACUC office: full committee review (FCR) and designated member review (DMR). All protocols are reviewed and approved by one of these methods even if they do not involve a formal grant proposal. The possible outcomes for FCR are approval, require modifications to secure approval, or withhold approval. The possible outcomes for DMR are approval, require modifications to secure approval, and return to FCR. In both methods of review, all IACUC members receive an electronic copy of the protocol for evaluation and comparison of congruency with the supporting grant, contract or sub-award. Any IACUC member can request FCR; a request by a single member results in the protocol being designated for



FCR at a scheduled meeting of the IACUC. At the same time, the IACUC Chair assigns a primary reviewer with specific assignments based on a rotational or expertise-linked basis from the IACUC membership. A member with a conflict of interest is recused from voting. Any minority opinion offered during the voting process is included in the IACUC minutes.

**FCR:**

Protocols that include issues of potential concern, including those proposing studies in USDA Pain/Distress category E, or involving multiple major survival surgery, or proposing the use of animals in medical education are administratively assigned for FCR by the IACUC Administrator. All members of the IACUC receive electronic copies of all submitted protocols and modification requests, and are invited to submit comments, questions or requests for revision of the submission within five working days. For protocols that are not administratively assigned for FCR, any member may during this period request that the protocol or modification request be assigned for FCR. If no such requests are made, then the protocol is transferred to the DMR pathway and the assigned primary reviewer becomes the designated member reviewer. For protocols that are reviewed by FCR, the assigned primary reviewer becomes responsible for presenting the protocol a convened meeting of the IACUC. If issues arise during the initial review prior to the convened IACUC meeting, the questions and concerns of the primary reviewer and/or from any other IACUC member, these are collated by the IACUC office staff into a clarification letter (i.e. a request for information/clarification), signed by the IACUC Chair, and sent to the PI. The PI is then required to respond to each of the comments and questions in a memorandum format and to submit a revised protocol to the IACUC office. Further clarification letters may be generated if the initial response(s) is/are deemed unclear or unsatisfactory by any IACUC member or if additional issues arise during the FCR. Communication is primarily accomplished electronically and all IACUC members receive a copy of each clarification letter, the PI's response, and any revised documents. The protocol is then scheduled for formal review at the next convened IACUC meeting. The IACUC may choose to invite the PI to attend the meeting to address further concerns; alternatively, the PI may ask to attend the meeting to address committee concerns. The PI may also send a representative if he/she is unavailable. The PI and any representatives leave the meeting prior to a final discussion of the submission and a formal vote of the committee on the protocol or modification request. If the PI's responses provided either in writing or at the IACUC meeting, do not satisfactorily address the committee's concerns, the IACUC may withhold approval of the protocol (by a majority vote of convened members) and a letter indicating that the approval of the protocol was withheld and the reasons for withholding are sent to the PI. The PI may appeal this determination in writing or by a further personal presentation to the IACUC for the IACUC to re-evaluate its decision. In practice, almost all concerns regarding protocols submitted to the IACUC have been settled by agreement following the PI's receipt of the IACUC letter.

If the members' concerns have been satisfactorily addressed prior to or during the convened meeting, the committee may vote to approve the protocol (by a majority vote of convened members). If concerns remain, the committee may vote to require modifications to secure approval (by a majority vote of convened members). In this case the PI will be notified of the required modifications in writing. The Chair may, with a majority vote of the convened members, use DMR subsequent to FCR. A reviewer with the appropriate expertise to ensure that the PI's changes fully comply with the IACUC's stipulations will be selected. All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR.

**DMR:**

DMR is used for protocols that are not assigned for FCR. All IACUC members receive a copy of the protocol electronically and have five working days to request FCR either in writing or via e-mail. If no member requests FCR, the Chair assigns the protocol for DMR. As for the FCR, the IACUC Chair assigns a primary reviewer on a rotational or expertise-linked basis from the voting members of the IACUC. Once assigned, the reviewer is given a further five working days to review the protocol. The questions from the reviewer and any other committee member are collated into a clarification letter and sent to the PI. The PI is required to respond to each of the comments and/or questions in a memorandum format and to submit a revised version of the protocol. The PI's responses and the revised protocol are then sent to all IACUC members; if there is any disagreement among the members that cannot be resolved, the protocol must be reassigned for FCR. If the primary reviewer does not receive any further expressions of concern from IACUC members, the protocol may be approved. Alternatively, the DMR reviewer may request additional modifications to secure approval or may refer the protocol to FCR.

Following approval by FCR or DMR, an approval letter is sent to the PI and a copy of the approved protocol is forwarded to the Office of Research for insertion into the project file. All protocols are approved for a period of three years; this is stated in the approval letter sent to the PI. Animal use may not be initiated until the PI receives written notification of approval ('start letter') from the IACUC and animal use on newly approved protocols may not begin until a protocol planning meeting, involving a face-to-face meeting between the PI, Chief of VSD/VMD, and appropriate LAM staff is conducted, and all training requirements have been met.

The IACUC weighs the potential adverse effects of the study against the potential benefits that may result from the research through evaluation of the Military Relevance section of the USUHS protocol template. Risk-benefit analysis is inherent in all IACUC protocol-related deliberations.

All protocols undergo the same level of review to include those with the potential for pain or distress. Veterinary input is solicited during the protocol pre-review process. The PI must describe considerations for refinement, reduction, or replacement of animal models. Those protocols that are anticipated to produce pain and/or distress, whether alleviated or unalleviated, are required to conduct a second literature search for alternatives to pain and distress. Justification for not using alternative methods must be included in the protocol. The rationale for the species proposed for use must be provided for review.

Animal or experimental group sizes are determined by statistical analysis and sample size calculations with power analysis. A statistical review of the protocol is required as part of the pre-review process. Additionally, a biostatistician serves as an IACUC member and sample size determinations are part of the protocol review process. Breeding protocols are required to explain breeding strategies to achieve desired number of offspring.

- ii. Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of "major" vs. "minor" amendments.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

#### Major Modifications

Major modifications to the original approved protocol are requested by submitting USUHS Form 3206B "Modifications of an Animal Study Protocol" to the IACUC office. A pre-review of major modifications by a LAM veterinarian is required before the protocol modification is sent to the IACUC members. The modification request is provided to each IACUC member for FCR or DMR consideration as described above. The submission must include a detailed explanation of the modification(s) requested. Any animal manipulation that changes the pain and distress category from what was originally approved must be justified and accompanied by a literature search for alternatives.

#### Minor Modifications

Minor modifications are submitted via email in the format designated in IACUC Policy #11. The IACUC Chair or his/her designee is granted authority by the IACUC to review minor administrative modifications and grant approval to those that meet the guidelines for minor administrative modifications. Minor scientific modifications are reviewed by the DMR process utilizing the AV or his alternate. A list of all minor modifications is presented to the committee at the monthly convened meeting and entered into the meeting minutes.

A description of major vs minor modifications is contained in IACUC Policy 11.

**c. Special Considerations for IACUC/OB Review** [*Guide*, pp. 5; 27-33]

**i. Experimental and Humane Endpoints** [*Guide*, pp. 27-28]

- 1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

IACUC review of animal use protocols includes evaluation for the close linkage of experimental and humane endpoints. The use of humane endpoints is stressed during protocol review with major input from LAM veterinarians. Humane endpoints are developed through literature searches, pilot studies, and PI experience. The protocol template contains a section related to endpoints which requires the PI to describe and justify study endpoints. Adjusted early endpoints (humane) are evaluated and approved during the protocol review process. The IACUC also evaluates protocols to ensure that animals are accurately grouped according to the appropriate USDA pain category. Death as an endpoint is highly discouraged and if requested, must be strongly justified and approved by the IACUC. A description of the monitoring procedures for when alternatives are not available must be included in the approved protocol.

- 2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special monitoring, other alternatives).

A description of the monitoring procedures for when alternatives are not available must be included in the approved protocol. Monitoring will occur through the reporting of abnormalities to LAM staff by the research team or through direct observation/monitoring by LAM staff with reporting to the IACUC as needed. Pilot studies are also considered.

- 3) Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

Monitoring procedures and personnel must be included in the approved protocol. All personnel involved in a study must show adequate training/experience to perform designated procedures or must be trained by appropriate LAM and/or investigative staff in species and protocol-specific monitoring for signs of pain and distress. Monitoring will occur through the reporting of abnormalities to LAM staff by the research team or through direct observation/monitoring by LAM staff with reporting to the IACUC as needed.

- ii. Unexpected Outcomes that Affect Animal Well-being** [*Guide*, pp. 28-29]  
Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

Animals housed within LAM are monitored daily by animal care and research personnel. Animals adversely impacted by unexpected outcomes may be identified by research or animal care staff. A LAM veterinarian is notified when the health and well-being of an animal is impacted. Reports of phenotypes affecting the health and well-being are made to research investigators and the IACUC for deliberation about further generation of the associated genotype. The AV and/or the PI report unexpected outcomes to the IACUC through notification of the IACUC Chair.

**iii. Physical Restraint** [*Guide*, pp. 29-30]

*Note:* This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

- 1) Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

All procedures requiring prolonged restraint are approved by the IACUC. If prolonged physical restraint is required by study design, a scientific justification and consideration of alternatives are required in the protocol. Restraint devices are not considered a normal method of housing. Restraint devices are not used simply as a convenience in handling or managing animals. The period of restraint should be the minimum required to accomplish the research objectives. Animals will be given training using positive reinforcement to adapt to the equipment and personnel. Any animals that fail to adapt will be removed from the study. The IACUC will assure observations of the animal(s) occur at appropriate intervals. LAM veterinarians will be contacted if behavioral changes, lesions, or illnesses related to the restraint device are detected. The PI is responsible for clearly explaining the purpose of the restraint and its duration to all personnel involved in the study.

- 2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe
- the duration of confinement
  - acclimation procedures
  - monitoring procedures
  - criteria for removing animals that do not adapt or acclimate, and
  - provision of veterinary care for animals with adverse clinical consequences.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

Studies requiring restraint of mice for irradiation studies involve placing the animal in a specially designed jig for 30-40 minutes while the animals are under anesthesia with ketamine and xylazine. Conscious prolonged restraint is not performed. Anesthetized mice are monitored and kept on a warm heating pad throughout the procedure.

Rats may be restrained in Plexiglas restraint tubes as part of an approved stress exposure component of research protocols. In these studies animals are placed in the restraint tubes designed to accommodate the individual animals' sizes. Electrodes are attached to the animals' tails where they then undergo a series of 40 3 second duration, 2 mA electric stimuli over a 2 hour period (range every 140-180 seconds). The tube may be adjusted slightly to allow the animal to adjust to a position that does not impede respiration. Animals are typically handled upon arrival and have not been shown to exhibit severe reactions to this procedure. If they do exhibit severe reaction to stimulus, the animals are withdrawn from the study.

#### **iv. Multiple Survival Surgical Procedures [Guide, p. 30]**

*Note:* One survival surgical procedure followed by a non-survival procedure is not included in this category.

- 1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

Multiple survival surgical procedures on a single animal are discouraged. However, under special circumstances, more than one major surgical procedure on a single animal may be permitted with the approval of the IACUC; provided they are related components of a research or instructional project; they are performed with adequate anesthesia; after-care is designed to alleviate post-surgical pain; and adequate post-operative care is provided. An exception to this policy is if one or more surgical procedures are required as a routine veterinary procedure or is to protect the health and well-being of the animal as determined by a LAM veterinarian. Animals are not permitted to be used in more than one protocol involving major survival surgery. Cost alone is not an adequate reason for performing multiple survival surgical procedures on an animal, but such procedures may be justified in the interest of conserving members of a rare species. Additionally, the USUHS IACUC recognizes that some procedures characterized as minor may induce substantial post-procedural pain or impairment and should be similarly scientifically justified if performed more than once in a single animal.

When multiple major survival surgeries are required and justified in the protocol, the following requirements must be addressed in the protocol and considered by the IACUC.

- A detailed description of the procedure(s)
- Assurance that the procedures do not permanently compromise the animal's ability to perform normal functions (e.g. eating, drinking, grooming, righting itself, etc.)
- Aseptic techniques and general anesthesia
- Post-operative care and the use of appropriate analgesics and antibiotics
- The animal must be allowed to recover fully from the effects of the previous surgical anesthesia and all physiological parameters must be within normal limits, unless variations are the result of approved surgical manipulations before the next surgical procedure is performed
- Personnel responsible for performing the surgeries and post-operative recovery must be identified

Protocols or protocol modifications involving multiple survival surgical procedures will be approved in accordance with protocol and modification approval processes involving FCR or DMR as previously described.

2) Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

In one study, "Intranasal insulin therapy for single and repeated mild traumatic brain injury," animals undergo stereotaxic surgery that includes application of a fluid percussion wave via cannula attached to the skull. For the repeated brain injury group, animals undergo the same procedure on the ipsilateral side 25 hours after the initial procedure.

v. **Food and Fluid Regulation** [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)

- methods of ensuring adequate nutrition and hydration during the regulated period

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

The majority of IACUC-approved food/water restriction is related to pre-procedural considerations, as outlined below:

Study	Justification	Species	Length and Type of Restriction	Monitoring	Nutrition/Hydration
(b)(2)	This study measures urine volume and concentration; must have controlled water intake for accurate measurements	Mouse	Water for 1-2 days; special diet with controlled fluid content, no additional water	Daily body weight, clinical signs (decreased skin turgor, lethargy, etc.)	Mouse are fed a special diet adequate for nutritional needs; previous studies show that these mice typically eat all of their diet and do well. Monitoring as previously noted.
(b)(2)	One objective of this study involves Intraperitoneal glucose tolerance test (IPGTT), and serum lipid and insulin measurements ; accurate measurement requires an overnight and 2 hour intra-procedural (IPGTT) fast.	Rat	Overnight fast	This length of time is not expected to result in adverse health conditions. However, any animals presenting with signs of illness (inactivity, signs of distress, weight loss >15%, etc.) will be removed from the study after consultation	Animals are fed ad libitum before and after the fasting period.



				n with veterinary staff.	
(b)(2)	This study involves total body irradiation requiring general anesthesia.	Swine	16-18 hours	While not a surgical protocol, the food restriction is similar to that for a surgical protocol (requires general anesthesia).	Temporary restriction. Animals are fed per normal husbandry practices before procedures and post-recovery.
(b)(2)	This study measures physiologic changes in mice fed high-fat diets	Mice	Fasted for 16 hours before glucose tolerance test; water available throughout	Routine health monitoring. Mice are also on reverse light cycle and therefore fasted during a period of reduced activity.	Temporary restriction with ad libitum water.
(b)(2)	Laparoscopic surgery	Swine	Overnight fast for surgery	While this study only involves pre-surgical fast, it was approved with food restriction. Included here for consistency with IACUC- approved protocol.	
(b)(2)	Study involves measurement of glucose,	Rat	Overnight fast for morning sample	Temporary restriction with no specific	Temporary restriction with no specific

	ketones, and lipids		collection. Unlimited access to water.	monitoring requirement .	monitoring requirement.
(b)(2)	Animals are fasted overnight to reduce stomach volume in preparation for orogastric inoculation.	Mouse	Fasted overnight; water restricted 1-4 hours pre-procedure.	Temporary restriction with no specific monitoring requirement .	Temporary restriction with no specific monitoring requirement.
(b)(2)	Animals are fasted with ad libitum water for 4 hours to reduce stomach volume in preparation for orogastric inoculation. After inoculation food and water are withheld for 1-2 hours to facilitate bacterial colonization.	Mouse and Gerbil	4 hours pre-inoculation (food): 1-2 hours post-inoculation (food and water)	Temporary restriction with no specific monitoring requirement	Temporary restriction with no specific monitoring requirement.
(b)(2)	Restricted feed necessary as motivation for lever press training.	Rat	16-20 hours of restricted feed, followed by ad libitum feeding for a few hours post-training session (sessions occur over 2-3 days)	Weight loss (more than 10% of body weight not re-gained over 48 hours, continuous weight loss of 5g/day over 5 days) and other signs of morbidity	Weight loss (more than 10% of body weight not re-gained over 48 hours, continuous weight loss of 5g/day over 5 days) and other signs of morbidity will be used to determine humane endpoints.

				will be used to determine humane endpoints	
(b)(2)	Animals are fasted overnight to reduce stomach volume in preparation for orogastric inoculation.	Mouse	Fasted overnight; water restricted 1-4 hours pre-procedure.	Temporary restriction with no specific monitoring requirement .	Temporary restriction with no specific monitoring requirement.

**vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances [Guide, p. 31]**

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

The use of non-pharmaceutical grade drugs is not allowed by the IACUC unless scientifically justified. The justification of non-availability of pharmaceutical grade compounds is assessed by the IACUC and approval of the use of chemical grade substances is made when appropriate. Factors of the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, are considered by the IACUC.

**vii. Field Investigations [Guide, p. 32]**

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

N/A

**viii. Animal Reuse [Guide, p. 5]**

- 1) Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

Animal reuse is requested and described in the protocol, which must be reviewed and approved by the IACUC. Reuse for a major survival surgical procedure is prohibited if the animal has previously undergone a major survival procedure. LAM veterinarians in conjunction with the PI determine if individual animals are suitable for reuse. An animal transfer request must be submitted to LAM for animal tracking. Tissues may be shared between researchers if previously approved in the IACUC protocol.

- 2) Briefly describe the types of activities currently approved that involve the reuse of individual animals.

*Note:* A list of specific protocols involving reuse of animals should be available during the site visit.

Currently, there are no approved protocols that involve reuse of individual animals.

- 3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.

*Note:* A list of specific protocols involving reuse of animals should be available during the site visit.

N/A

## 2. Post-Approval Monitoring [Guide, pp. 33-34]

- a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

Inherent functions of the IACUC and LAM provide protocol oversight and assure protocol compliance. The IACUC approves protocols for a period of three years. Protocols that will continue beyond this period are required to undergo a triennial review. The review and approval process is the same as that of a new protocol (de novo review). A new literature search must be conducted to check for duplication and for alternatives to any procedures classified as USDA pain category D or E.

The PI is required to submit a USUHS Form 3206A, "Annual Review of Animal Study Protocol" (Appendix 7) for each approved protocol. All members of the IACUC receive an electronic copy of the form to review, but primary review and approval authority is assigned to one of the LAM veterinarians and to the IACUC Chair. Annual reviews are included for a final approval vote at the monthly IACUC meeting.

The IACUC conducts semi-annual program reviews and facility/laboratory inspections which includes protocol files, animal records, animal housing, procedure rooms and logs, etc.

The LAM veterinary and animal care staffs, in the performance of their assigned duties, provide oversight of animal welfare and protocol compliance. LAM personnel are involved with the daily care of animals and provide support or may directly perform experimental procedures. Protocols are reviewed by LAM staff prior to

providing support to researchers. Unexpected outcomes, adverse events, or instances of protocol non-compliance are reported to the AV and subsequently to the IACUC.

- b. Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

The IACUC conducts semi-annual program reviews and facility/laboratory inspections. Subcommittees, composed of at least two members, are used to evaluate the program and assigned areas within the animal facility or laboratories. All members are invited and encouraged to participate. The IACUC uses the "Semi-annual Program Review and Facility Inspection Checklist" from the OLAW website. Additionally, DD Form 2856, "DOD Semiannual Program Review/Facility Inspection Checklist" is completed. Deficiencies noted during the review are classified as minor or significant. A plan for correcting the deficiency is proposed along with a timetable for correction. Deficiencies are reported at each subsequent IACUC meeting until corrected. A report including noted deficiencies and correction plans, exceptions to the AWR or Guide, and any minority opinions is prepared for approval by the IACUC and submitted to the IO. The report is signed by a majority of the IACUC members.

- c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.
- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
  - If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.
- Note:* A copy of the last report of these reviews should be included as **Appendix 10**.

The IACUC conducts semi-annual program reviews and facility/laboratory inspections. Subcommittees, composed of at least two members, are used to evaluate the program and assigned areas within the animal facility or laboratories. All members are invited and encouraged to participate. The IACUC uses the "Semi-annual Program Review and Facility Inspection Checklist" from the OLAW website. Additionally, DD Form 2856, "DOD Semiannual Program Review/Facility Inspection Checklist" is completed. Deficiencies noted during the review are classified as minor or significant. A plan for correcting the deficiency is proposed along with a timetable for correction. Deficiencies are reported at each subsequent IACUC meeting until corrected. A report including noted deficiencies and correction plans, exceptions to the AWR or Guide, and any minority opinions is prepared for approval by the IACUC and submitted to the IO. The report is signed by a majority of the IACUC members.

- d. If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies.
- Note:* Copies of all such inspection reports (if available) should be available for

review by the site visitors.

A site inspection was conducted on December 7, 2016 by the U.S. Army Medical Research and Materiel Command's Animal Care and Use Review Office. The final report was received March 2017 and is under review for appropriate corrective actions. A copy of the inspection report will be available on-site. In summary, our program was deemed to be in compliance with federal regulations and the Guide. Most of the findings/suggestions involved general housekeeping, minor facility repairs, and administrative/documentation inconsistencies with several findings already considered and implemented. One finding was considered significant, which was the lack of pest control in three areas: surgery rooms, satellite housing spaces, and an irradiation room.

- e. Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

N/A

**3. Investigating and Reporting Animal Welfare Concerns** [*Guide*, pp. 23-24]

Describe institutional methods for reporting and investigating animal welfare concerns.

The IACUC, its Administrator, its Chair or Vice Chairs, or any member of the IACUC may receive reports of possible deviations from approved IACUC protocols or concerns related to the welfare of animals used for research or education at the Uniformed Services University (USU) from any person in the University. This document defines the procedures to be followed in investigating and evaluating such reports and how such events will be reported to oversight bodies including the NIH Office of Laboratory Animal Welfare (OLAW) and the US Army Animal Care and Use Review Office (ACURO).

1. Any person at the USU may raise an issue of concern relating to the welfare of laboratory animals or of possible deviations from approved animal research or teaching protocols. Such concerns should be brought to the attention of the Chair of the IACUC, the IACUC Administrator, the Attending Veterinarian, or any member of the IACUC. Signs indicating to whom animal welfare concerns should be directed are located throughout the USU central animal facility.

2. Once a concern is raised, the IACUC Chair or his/her designee (e.g., a Vice-Chair), acting in consultation with the Attending Veterinarian (AV; or his/her designee) and the Institutional Official (IO; or his/her designee) shall make an initial decision on whether the concern is substantial, necessitating reporting to OLAW or ACURO, or whether the issue does not rise to the level of a reportable incident under the requirements of the Animal Welfare Act.

3. If the incident or concern is deemed not reportable in this initial evaluation, the IACUC Chair and AV shall consider whether any action is required to address future concerns of a

similar nature. The IACUC Administrator will keep a record of concerns that are brought to the IACUC Chair and AV, including concerns that are ultimately deemed not reportable.

4. If the incident or concern is deemed reportable to OLAW & ACURO, an initial incident report, briefly outlining the incident of concern, will be prepared by the IACUC Chair or designee, in consultation with the AV and IO, and sent electronically to the OLAW Office of Compliance and ACURO. The report will note that the incident or concern is under review and that a final report will be sent indicating actions taken in response to the incident or concern will follow.

5. The IACUC Chair may either appoint a subcommittee to review the incident/concern or may refer the incident directly to a scheduled meeting of the IACUC. A subcommittee, if appointed, will be comprised of at least two primary or alternate appointed members of the IACUC and a veterinarian appointed by the AV (unless the AV and his staff are in conflict in relation to the incident). The subcommittee may also include members of USU faculty with appropriate knowledge or experience who are not appointed members of the IACUC.

6. If a subcommittee is appointed, the subcommittee will evaluate the incident/concern, and prepare a written report for submission to the IACUC summarizing the incident and containing recommendations for avoiding similar incidents or expressions of concern in the future. The recommendations may include changes in procedures related to either research or animal husbandry and may include sanctions for the Principal Investigator and/or his/her staff on the relevant IACUC protocol. The IACUC will review the recommendations of the subcommittee, and members may propose revisions to the recommendations. The IACUC will vote on whether to accept the final version of the recommendations.

7. If a subcommittee is not appointed, the full IACUC will consider what actions need to be taken to avoid similar incidents, including sanctions for the Principal Investigator and/or his/her staff on the relevant IACUC protocol, if deemed appropriate. The IACUC will vote on whether to accept the final version of the recommendations.

8. The IACUC Chair will oversee the implementation of the IACUC recommendations for actions relating to the incident/concern, in conjunction with the IACUC Administrator and/or the AV.

9. Once the recommended actions in response to the incident/concern have been implemented, the IACUC Chair, in consultation with the AV if appropriate, will draft a final report of the incident for review and approval by the IO. The IO will submit a printed and signed version of the final report to the OLAW Office of Compliance, with a copy submitted to ACURO. The IACUC Administrator will maintain copies of the final report in the IACUC records.

#### **4. Disaster Planning and Emergency Preparedness [Guide p. 35]**

Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:

- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

*Note:* A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

The University Emergency Operations Plan, Instruction 3000 and the Center for Laboratory Animal Medicine Emergency Operations Manual contain detailed information on types of emergencies likely encountered and action plans for those emergencies. These documents are available for review on-site. Disaster planning is an integrative process involving all levels of University, including individual preparedness. During a disaster affecting the animal care and use program, human safety is of utmost concern. The animal population will undergo a triage process including assessments of health, need for treatment(s), need for euthanasia, loose/escaped animal, and individual room hazards. Animals may be moved, if necessary, to another Department of Defense research facility, if possible. All activities are coordinated with University and Naval Support Activity Bethesda emergency personnel.

## **II. Animal Environment, Housing and Management**

*Note:* Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

### **A. Animal Environment**

*Note:* Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11**.

#### **1. Temperature and Humidity [Guide, pp. 43-45]**

- a. Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

Animal room temperature and humidity are monitored at least once daily by AHD personnel and VMD. The current temperature/humidity and the high and low temperature/humidity for the previous 24 hours are recorded by AHD personnel. A calibrated, battery-operated thermometer/hygrometer device with high/low recording capability is maintained in every animal holding room and are recalibrated quarterly



with a second electronic thermometer/hygrometer. Temperature and humidity are also monitored centrally through the Facilities Department's HVAC monitoring system.

- b. List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.

*Note:* If preferred, this information may be provided in a Table or additional Appendix. [Guide, pp. 44 and 139-140]

The set points for the currently housed species are as follows: Rodents – 68-79°F, Rabbits – 61-72°F, Swine – 61-81°F, and Ferrets – 65-79°F.

- c. Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [Guide, p. 43]

There are no set points outside of the thermoneutral zone for any species. If the ability to provide heat or cooling to animal was compromised, portable heaters or fans are available. Additionally, extra bedding may be provided if temperatures are too low.

## 2. Ventilation and Air Quality [Guide, pp. 45-47]

- a. Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

Room ventilation rates are monitored annually and documented by Facilities. Professional air balancing is performed at least once every three years. This testing is inclusive of confirming air exchange rates, verifying minimum and maximum cfm with respect to design, and verifying correct directional air flow.

- b. Describe ventilation aspects of any special primary enclosures using forced ventilation.

The USUHS uses (b)(6) and (b)(4) ventilated units and laminar flow units in some rooms. Units are rated at between 30 and 100 (60 is optimal performance) air changes per hour, depending on rack static pressure. There are currently 13 (b)(6) units, 9 (b)(6) and 2 (b)(4) units in use. One hundred percent fresh air enters the CAF rooms. The air enters each cage through a pre-filter and a high efficiency particulate air (HEPA) filter. Air leaves the cage based on heat from waste gases and the system's negative air pressure compared to the

animal holding room. Exhausted air is also HEPA filtered. The closed-system design is characterized by one-pass airflow across the cage. Air from the (b)(4) units is exhausted back into the room.

- c. If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

Air is supplied throughout the facility at a design air flow rate of 10-15 air changes per hour of 100% fresh air.

### 3. Life Support Systems for Aquatic Species [Guide, pp. 84-87]

- a. Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

N/A

- b. Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.

*Note:* Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

N/A

### 4. Noise and Vibration [Guide, pp. 49-50]

Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

Noise from husbandry and other procedures in the animal rooms is kept to a minimum. Foot traffic is limited within the CAF. Room construction and the use of metal doors minimize noise from the hallway and other rooms. Personnel are not permitted to use equipment generating high or low frequency sounds that may affect the animals in occupied rooms. The animal rooms are located an appropriate distance from cage washers, HVAC system, and other mechanical devices, and are not exposed to vibration from these systems.

## B. Animal Housing (all terrestrial, flighted, and aquatic species)

## 1. Primary Enclosures

*Note:* A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 13**.

- a. Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

The *Guide for the Care and Use of Laboratory Animals*, 8th edition is used by the IACUC to verify adequacy of space provided for all research animals.

- b. Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

At present there are no exceptions at USUHS to the policy of the recommended minimum space indicated by the *Guide*. Requests for exceptions would be reviewed by the IACUC on a case-by-case basis. Ongoing post-approval monitoring by the AV or designee and research personnel would occur to analyze animal well-being.

## 2. Environmental Enrichment, Social, and Behavioral Management [*Guide*, pp. 52-55; 63-65; *Ag Guide*, Chapter 4]

### a. Environmental Enrichment

- i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

Pig pens contain an elevated grate above the pen floor for resting. Rabbit cages contain an elevated resting board.

- ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

Environmental enrichment for rodents includes bedding, nestlets, igloos, (b)(4) Mouse Retreats, and chew toys. Pigs and goats have balls and other toys for stimulation. Ferret cages contain a nesting box and hammock as well as various toys. A playpen contains tubes for the ferrets to explore. Rabbits may be enriched in large pens with bedding, litter pans (filled with hay) and toys.

All toys are rotated at least weekly.

**b. Social Environment** [*Guide*, p. 64]

- i. Describe institutional expectations or strategies for social housing of animals.

The default institutional policy is to pair or group house all social species.

- ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

Protocol-specific, veterinary, or incompatibility issues may necessitate individual housing. If animals must be individually housed, it will be for the shortest time possible.

- iii. Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

If an animal is singly housed, additional enrichment items are provided along with daily human interaction, when possible. Most animals are housed in cages or pens that are adjacent to conspecifics and allow visual and olfactory stimulation.

**c. Enrichment, Social and Behavioral Management Program Review** [*Guide*, pp. 58, 69]

Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

The IACUC reviews and approves all exceptions to the environmental enrichment policy based on justification in the submitted protocol. The IACUC reviews environmental enrichment exceptions during annual protocol reviews and semi-annual facility inspections and program review to ensure they are beneficial to animal well-being and consistent with the goals of animal use. LAM staff evaluates animals on a daily basis and will detect if there are adverse consequences to environmental enrichment exceptions. Animal welfare issues will be brought to the attention of the PI and the IACUC.

**d. Procedural Habituation and Training of Animals** [*Guide*, pp. 64-65]

Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

Animals housed at USUHS are purpose bred in dedicated facilities and programs for research. The animals are allowed to acclimate for at least 3 days after arrival. They are housed with or next to conspecifics. Handling of animals only occurs by individuals trained to properly care for and use the species. Gradual exposure to routine husbandry and experimental procedures is encouraged within LAM whenever possible. Animals are monitored for signs of stress during husbandry and experimental procedures. Animal caretakers are assigned to particular holding rooms, so that staffing changes between rooms are kept to a minimum.

**e. Sheltered or Outdoor Housing** [*Guide*, pp. 54-55]

- i. Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

N/A

- ii. Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

N/A

- iii. Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

N/A

**f. Naturalistic Environments** [*Guide*, p. 55]

- i. Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

N/A

- ii. Describe how food, water, and shelter are provided.

N/A

iii. Describe how animals are captured.

N/A

C. Animal Facility Management

1. Husbandry

a. Food [Guide, pp. 65-67]

i. List type and source of food stuffs.

(b)(4)	uminant Diet	(b)(2)
	ouse Irradiated Breeder Diet	(b)(2)
	abbit Global Hi Fiber Diet	(b)(2)
	odent Low Protein Diet	(b)(2)
	odent Diet	(b)(2)
	ig Diet	(b)(2)
	lobal Certified Ferret Diet	(b)(2)
	Mouse Diet, Helicobacter, 4 Drug Combo-Sterile	
Fresh produce is obtained from the (b)(2); (b)(4)		

ii. Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

The vendor stores feed in climate-controlled environments on pallets and rotates stock according to manufacturing dates by the "first-in, first-out" rule of inventory management. Warehouses are completely sealed and have floor/wall perimeters that have been painted white to allow for accurate visual inspection of cleanliness and also to prevent stock from coming within 18" of the wall. Facilities are inspected and cleaned on a daily basis. Transport trucks are cleaned using a sterilant/disinfectant, MB-10, after each delivery. Temperature never exceeds 70°F and humidity never exceeds 55%. Both temperature and humidity are monitored and recorded daily. Professional exterminators provide pest control. Quality control results from testing performed by the manufacturer are available upon request or are provided with each shipment. Vendors are visited and inspected by LAM staff members upon initial award of the contract as required by military

regulation. The (b)(2); (b)(4) is inspected on a monthly basis by the US Army Veterinary Corps and reports are available upon request.

All feed is stored in Room (b)(2) on plastic pallets at least four inches off the floor and six inches away from the wall. The feed room environmental controls maintain a temperature range of 65-70 degrees Fahrenheit, and are monitored by LAM personnel. Feed in animal rooms is stored in airtight, water-proof, vermin-proof containers labeled with the feed mill date, date bag is opened, and container sanitation date. New feed is not placed on top of old feed; either the feed container is emptied or the remainder of the feed is discarded. A freshly sanitized container is placed in the rooms prior to placing fresh feed in them. Feed containers are replaced and sanitized when the container is empty. Vermin control effectiveness is monitored through the use of insect sticky traps. As in the entire CAF, the pest management contractor provides evaluation and treatment if needed.

- iii. Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

N/A

- iv. Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Feed is provided to animals using specific feeders. Stainless steel bowls and trays are used for pigs, ferrets, and rabbits housed in runs. Rabbits housed in cages are provided stainless steel "J" feeders. A stainless steel "J" feeder or wire cage tops are used for rodents. Animals, other than rodents, receive a fresh daily ration. Rodents receive fresh feed during cages changes or as needed if feed supply has been exhausted. All animals are fed *ad libitum* unless a specific diet or amount is required by an IACUC-approved protocol.

- v. Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

All feed bags are inspected upon receipt. Any bag that is opened or damaged is discarded. The feed milling date is checked upon arrival. Feed milled more than 40 days prior to receipt is not accepted and lots older than six months from milling date are discarded. Feed stock is rotated to ensure that feed with the earliest milling date is used first. Milling dates are monitored upon arrival and whenever feed is transferred to animal room, or when feed is replaced. Quarterly quality

assurance feed samples are submitted to the Food and Animal Diagnostic Laboratory, Ft. Sam Houston, TX, for proximate analysis. Quality assurance results are maintained in the VMD technician office.

**b. Drinking Water** [*Guide*, pp. 67-68]

- i. Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

The Washington Suburban Sanitary Commission supplies water from the Potomac River Filtration Plant. The CAF has 0.5-micron filters on all automatic waterers and the water bottle filling station. The water meets or exceeds Safe Drinking Water Act requirements. Water via the automatic system is delivered at a controlled, reduced pressure through pressure-reducing and filtration stations that service animal rooms (large animal rooms only). Rodents are provided water in water bottles with sipper tubes. Water, water bottles, stoppers and sipper tubes are assembled and autoclaved for all rodents in the barrier or as needed for rodents in the conventional areas of the CAF. Acidified water for specific protocol support is acquired from AFRR1. Fresh, potable, municipal water is provided on a continual basis to all large animals via lixits. Stainless steel bowls or water bottles may be used if necessary for large animals. Newly arrived pigs and goats may have their lixits temporarily lodged in the trickle position to facilitate water consumption. Water bowls are changed daily. Automatic watering systems are checked twice daily at both the room and cage (lixit) level to ensure proper function. Large animals are checked twice daily to ensure water bowls or bottles are full.

- ii. Describe methods of quality control, including monitoring for contaminants.

Quarterly water samples are submitted to the Food and Animal Diagnostic Laboratory, Ft. Sam Houston, TX, for quality control testing. Samples are tested for inorganics, *Pseudomonas*, turbidity, and coliforms.

- iii. If automatic water delivery systems are used, describe how they are maintained and sanitized.

Each week when animals are present the water lines, recoil hoses, and lixits in each room are chlorinated using an (b)(4) portable sanitation system and then flushed manually. Water lines are chlorinated and flushed before animals are placed in a room and when the room has been vacated. Water filters are changed monthly. Filters have cards attached which annotate the change date.

**c. Bedding and Nesting Materials** [*Guide*, pp. 68-69]



i. Describe type(s) and how used for various species.

Sani-chip and Aspen bedding (b)(4) are used for contact applications in all rodents and ferret nest boxes. Both are hardwood, heat-treated bedding materials. Sani-chip is used as non-contact bedding in suspended rabbit pans. Alpha-dri (b)(4) is also used to house nude mice and other animals, as deemed necessary by veterinary or research considerations. Piled strip paper bedding is used in the ferret play area.

ii. Describe bulk bedding storage facilities, if applicable, including vermin control measures.

N/A

iii. Describe quality control procedures, including monitoring for contaminants.

Upon delivery, bags of bedding are inspected for signs of damage; any questionable bags are rejected. No open bags are accepted. As bags are opened, personnel check for evidence of gross contamination, including insect infestation. The bedding for immune-suppressed animals is autoclaved prior to use. Quarterly bedding samples are submitted to the Food and Animal Diagnostic Laboratory, Ft. Sam Houston, TX, for quality control testing. Samples are tested for coliforms.

d. Miscellaneous Animal Care and Use Equipment

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

LAM has a dedicated van that can be signed out from the motor pool and is used exclusively for animal transportation. The van has been customized for animal transport. It is a converted 12 passenger transport van where the driver's compartment is separated from the animal compartment by a panel to protect against exposure to allergens or zoonoses. The animal compartment has separate heating and cooling to regulate the temperature. A stainless steel cage has been built into the animal compartment for transporting larger animals. The cargo area has the ability to anchor cages for safety of the animals during transport. The animal compartment is designed for easy sanitation.

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

Wet-dry HEPA-filtered vacuums, floor buffers, high pressure spray washer, (b)(4) caging systems, (b)(4) unit laminar flow workbenches, (b)(4) floor scrubbing machines, biological safety cabinets (Type II A and A/B3), bedding dump station, (b)(4) waste conveyor system, (b)(4) 1000 water bottle filling station, (b)(4) dual head bottle filling station, (b)(4) portable automatic watering sanitation system.

**e. Sanitation** [*Guide*, pp. 69-73]

**i. Bedding/Substrate Change**

- 1) Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Conventionally housed mice and rats in polycarbonate microisolator cages are changed twice per week. Rodents in IVC units are changed once per week. Cages found excessively soiled or wet are changed immediately. Rabbits in cages are housed above slotted pans; the pans are changed three times per week. Rabbit and ferret cages are changed at least weekly. When rabbits are housed in runs, floors are swept daily and rabbits are moved to clean runs weekly.

- 2) Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

N/A

- 3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

The cages and pans used by rodents, ferrets, and rabbits are scraped into a waste conveyor system that transports waste to an outside dumpster. In BSL 2 rooms housing rodents, cages/pans of soiled bedding are bagged, labeled, and sprayed with MB-10 disinfectant before being removed from the room to be autoclaved. Autoclaved bags are then emptied into trash bags inside the dump station on the dirty side of cage wash (Room (b)(2)). The bags are then placed in a large utility trash bin, covered and transported to and deposited in the designated outside dumpster. Clean bedding is placed in cages or pans on the clean side of the cage wash area.

**ii. Cleaning and Disinfection of the Micro- and Macro-Environments**

*Note:* A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

- 1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

Rodent breeding colonies and ferrets with kits may be on a delayed cage changing schedule to enhance survival and viability of newborns. In general, cages housing new rodent or ferret litters are left undisturbed for the first week following the date of birth unless sanitation is deemed unacceptable by the veterinary staff.

- 2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

- a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

Each cage washer is equipped with a temperature-recording device to monitor water temperature. The machine will not operate until the optimum water temperature is reached by the machine's temperature sensor. Temperatures are verified through periodic temperature tape checks. This information is logged on an equipment log sheet. The detergent vendor performs quality assessment procedures on their dispensing when they deliver chemicals, approximately every monthly. An equipment operator performs daily routine maintenance on all equipment and performs system checks at the beginning of the day. Problems with the equipment are reported immediately to the AHD Chief. The Chief, AHD also performs monthly assessments of cages, equipment and rooms by use of the ATP bioluminescence detector (i.e. (b)(4) luminometer). Sanitation of specialized caging or equipment utilized by researchers in laboratories or procedures outside the CAF and which are unable to be sanitized in LAM's mechanical washer are sanitized by hand and assessed by the research staff for effectiveness using a (b)(4) luminometer belonging to the CNRM.

- b) Describe preventive maintenance programs for mechanical washers.

Equipment operators perform daily routine maintenance on all equipment and perform system checks at the beginning of the day to include cleaning filters, trays, and adding salt to the water to reduce hardness. Problems with

the equipment are reported immediately to the AHD Chief. The manufacturer provides monthly preventive maintenance checks.

**f. Conventional Waste Disposal** [Guide, pp. 73-74]

Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

**i. Soiled bedding and refuse.**

All non-infectious waste is discarded daily. Soiled bedding from rodent cages and pans is disposed of in the waste conveyor system. Other non-biological refuse resulting from animal care and use in the CAF is deposited in trash receptacles with liners throughout the facility. Trash bags are collected and transported on a cart to the designated dumpster outside (b)(2). The dumpster is deposited in emptied by a private contractor and then deposited in the county waste dump.

**ii. Animal carcasses.**

All animal carcasses, tissues, and fluids are handled as Special Biomedical Waste in accordance with DOD guidelines and all applicable federal, state, and local laws. (b)(4) a subcontractor of (b)(4) removes the biohazard waste containers to include sharps containers twice weekly for incineration. Large animals, over 50 lbs, are removed by (b)(4). All carcasses, tissues, and fluids for disposal are placed in two heavy-duty plastic, red biohazard bags, labeled according to guidelines, and placed in a designated freezer located in the CAF.

**g. Pest Control** [Guide, p. 74]

**i. Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:**

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

An integrated pest management program is provided by an independent contractor, and overseen by the LAM Resource and Operations Manager. The pest control program consists of weekly facility inspections and monitoring through the placement of dated sticky traps in strategic locations within the animal facility spaces. A log is maintained by the contractor of pests detected on the traps and treatments, if any, performed during the weekly visit. Treatment options for commonly encountered pests may include sealing entry points, vacuuming, caulking, gel and dry baits, boric acid dust, trapping, expandable foam, and

pesticides. The following pesticides may be considered for use depending on the nature of the specific infestation:

Advance Granular Ant Bait - avermectin  
Advion Cockroach bait - Indoxacarb  
Advion Ant Bait – Indoxacarb  
Arilon - Indoxacarb  
Avert Gel Bait - avermectin Contrac - bromadiolone Delta Dust - deltamethrin  
Demand CS - lambda cyhalothrin DiTrac Tracking Powder - diphacinone Drione -  
pyrethrum + silica aerogel First Strike Soft Baits - difethialone Gentrol –  
Hydroprene  
Green Dragon cockroach bait gel – boric acid  
Max Force Gel - hydramethylnon  
Maxforce Professional Ant Bait - hydramethylnon  
Microcare-microencapsulated pyrethrin  
Mosquito bits – Bacillus thuringiensis  
Niban FG - boric acid (interior crack and crevice) Phantom aerosol – chlofenapyr  
PT P.I. - pyrethrins  
Termidor SC – fipronil  
Vendetta Plus – abamectin + pyriproxyfen  
Wasp and Hornet Jet Freeze  
565 Plus XLO – pyrethrins  
Gentrol (IGR - hydroprene)  
Precor (IGR - methroprene)

- ii. Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

N/A

- iii. Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

The pest management technician is required to obtain approval from the Director, LAM before the application of any chemical treatments in an animal housing area. Pesticides MAY only be used after consultation with concerned PIs and approval by the Director, LAM. If the pest management control program requires application of a pesticide in any or all areas, LAM will provide electronic notification to all investigators with specific information of the intent to treat the designated area for pests before employing new or volatile chemicals. LAM veterinarians will make every effort to personally discuss the proposed pesticide use with investigators that will be affected to assure research is not impacted. Investigators may opt out of use after consultation with a LAM veterinarian and if it is determined it will not negatively impact the facility.

**h. Weekend and Holiday Animal Care** [*Guide*, pp. 74-75]

- i. Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

Members of the LAM staff are scheduled on a rotational basis to provide weekend and holiday care of laboratory animals. All emergency, weekend, and holiday care is provided by two animal caretakers, a veterinary technician, and the on-call veterinarian. Weekend and holiday husbandry practices are reduced to essential tasks including feeding and watering of all animals and routine sanitation in large animal holding rooms. Cage changes only occur if cages are excessively soiled or wet. The veterinary technician performs rounds (health and welfare checks) on all animal rooms once daily. The veterinary technician also performs all medical treatments. The on-call veterinarian is notified when rounds are completed or if any animal or facility problems are identified.

- ii. Indicate qualifications of weekend/holiday staff if not regular staff.

N/A

- iii. Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

During normal duty hours, LAM veterinarians, and technicians can be contacted through the LAM Administrative office, by telephone or email, or in-person. After hours and on weekends and holidays, the on-call technician and veterinarian are available via telephone to respond to veterinary medical and facility emergencies. The veterinary duty roster is posted on the board in the (b)(2) corridor and in the administrative area of LAM. The University's security office, which is staffed 24hr/day, maintains a telephone list of key LAM personnel to contact in case of an emergency and is provided a copy of the duty roster.

**2. Population Management** [*Guide*, pp. 75-77]

**a. Identification**

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

Cage cards are used as the primary means of identification for rodents. Following confirmation of vendor, species, strain and number of animals, rodents are removed from the shipping crate and sexed. Each cage of animals has a cage card placed in the cage card holder. The information contained on the cage card may vary by species, but basically includes: Principal investigator's name, protocol number, receipt date, vendor, animal ID number/cage number, species/strain, gender, room location, and PI

contact information. Individual investigators may add a secondary identification system other than the cage card, such as indelible ink, ear tag, ear punch, etc. Animals produced under breeding protocols receive cage cards at the time of weaning.

All non-rodent animals have a computer-generated cage card which contains the following information: Principal investigator's name, species, sex, source, date received, animal number, protocol number, age/weight, and PI contact information. Individual animals are identified as follows:

Ferrets – arrive with an abdominal tattoo or ear tag

Rabbits – initially identified by writing the individual animal number on the inner pinnae of the ear with permanent marker. Rabbits that are housed long term are tattooed under anesthesia after coordination with the PI.

Swine- arrive with ear tags, ear notches, or tattoos.

## **b. Breeding, Genetics, and Nomenclature**

- i. Describe the program for advising investigators on the selection of animals based on genetic characteristics.

A LAM veterinarian reviews all animal use protocols prior to IACUC submission. LAM veterinarians routinely consult with investigators during the protocol planning stage about desired genetic characteristics to support the protocol. LAM will provide online database search assistance to PIs for the selection of new strains or genetic mutants.

- ii. Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of all animals used in a study.

A LAM veterinarian reviews all animal use protocols prior to IACUC submission. LAM veterinarians routinely consult with investigators during the protocol planning stage about appropriate nomenclature. Standardized nomenclature is used during animal ordering. Investigators are encouraged to use standard nomenclature for rodents, which follows the rules of both the Committee on Standardized Genetic Nomenclature for Mice and the Rat Genome and Nomenclature Committee. A listing of nomenclature for all strains used in the animal facility is available to all users through the vendor catalogs and websites.

- iii. Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Breeding and genetic records are maintained by the principal investigator or designee. Genetic identification/verification methods are in accordance with approved protocols and Institutional policies, and may include genotyping by various accepted methods (blood, tail snip in young mice, etc.).

- iv. For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

New genotypes developed at USUHS are observed by research and LAM staff for evidence of phenotypes that negatively impact animal well-being. Adverse phenotypes are reported to a LAM veterinarian for assessment and management. Reports of phenotypes affecting the health and well-being are made to research investigators and the IACUC for deliberation about further generation of the newly generated genotype.

### III. Veterinary Care [*Guide*, pp. 105-132]

*Note:* Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

#### A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

##### 1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

Reputable vendors for each laboratory animal species are screened and selected as approved sources. USDA-covered species are procured from USDA-licensed vendors. Vendors must provide, on request, current background information on animal production and maintenance, facilities, husbandry, veterinary care, disease surveillance and control, and personnel. Any researcher that requires an animal from an unapproved source must submit a request to the Chief, Veterinary Medicine Division. Only after approval by a LAM veterinarian based on a health history assessment for the individual animal or colony may the animals be ordered. All animals from unapproved sources undergo a quarantine period as determined by a LAM veterinarian and are removed from quarantine after applicable test results are obtained. Rodents are sometimes evaluated for quality assurance. Evaluation includes gross necropsy, histopathology, parasite examination, and serology. Physical examinations of animals are performed upon arrival.



## 2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

Transportation to the University occurs in vendor or contract carrier-owned, climate-controlled vehicles. Animals arrive at the (b)(2) loading dock. The vendor's driver off loads the animals and they are received in room (b)(2) by LAM staff. LAM Staff may assist with removing larger animals from the truck. Rodent crates/shipping containers are examined for structural defects and sprayed down with disinfectant (MB-10). All large animals are initially examined by the veterinary staff and then transported to their assigned rooms on carts or in transportation cages. Rodents are examined by AHD staff and notify veterinary personnel if there are any concerns. Within USUHS rodents are transported in cages on carts with a drape. Large animals are transported in dedicated transportation cages. Animals that are transported through USUHS are transported in designated elevators and designated corridors.

Animals may be transported from USUHS to another facility in a government-owned, climate-controlled van dedicated for animal transport. Animals may also be transported via commercial courier. Rodents are transported in filter top caging that contains a water bottle, pelleted rodent chow, and bedding. Research staff is responsible for loading of the animals. Other species may be transported in appropriate carriers, cages for that species.

## B. Preventive Medicine

### 1. Animal Biosecurity [Guide, pp. 109-110]

- a. Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

A bio-exclusion list for rodent and rabbit pathogens is used to pre-screen health reports from non-approved vendors and universities. Prior to uncrating, rodent and rabbit health reports are reviewed by a veterinarian or designee, to confirm health status.

The health of the rodent colonies is monitored through an ongoing sentinel program. Rodent dirty bedding sentinels are housed and sampled quarterly. Sentinel animals are placed in each mouse and rat room at the rate of two/70-80 cages of colony animals. The animals are placed on the lowest rack shelf and exposed to room air and dirty bedding retrieved from soiled cages at change outs. Evaluation includes histology, bacteriology, parasitology, and serology.

Large animals receive semi-annual physical examinations and fecal flotations. Blood work, to include complete blood counts and serum chemistries, may be performed at the discretion of a veterinarian.

**b. Describe methods used to control, contain, or eliminate infectious agents.**

The first approach to control infectious agents is to only allow animals from approved sources to enter LAM. Prior to approving the shipment of animals from other sources, health reports are requested and evaluated by a LAM veterinarian. Current health reports should accompany animals that are received from vendors.

Rodents are housed in microisolator or in individually ventilated cage racks to prevent the transfer of infectious agents. Rodent cages are opened in biosafety cabinets or laminar flow hoods to limit transmission.

LAM has a policy of not allowing individuals exposed to other laboratory rodents or feral animals to enter the CAF on the same day. Any exceptions must be reviewed and approved by LAM veterinarian after conducting a risk assessment.

No specific isolation or quarantine facility or area exists; however, each room can individually become a quarantine or isolation room based on animal care processes. If a LAM veterinarian suspects a potentially infectious pathogen, the room is quarantined and restricted access and decontamination procedures are instituted. Animals may be euthanized, treated and tested, cross-fostered, or rederived depending on the type and severity of the pathogen and research value of the animal.

**2. Quarantine and Stabilization [Guide, pp. 110-111]**

**a. Describe the initial animal evaluation procedures for each species.**

All non-rodent animals are delivered to the University and received in a room <sup>(b)(2)</sup> where they are initially examined by the veterinary staff. Animals that do not meet contract specifications are returned to the vendor. At receipt, rabbits, ferrets, pigs are given a physical examination by the veterinary staff. Health records are established. Then animals are then transported to their assigned cage/run and identified with a cage card.

Rodents arrive in filter crates equipped with a water source and cubes of appropriate feed. Crates/shipping containers are examined for structural defects and sprayed with disinfectant (MB-10). The rodents are then brought to the appropriate housing rooms and placed in microisolator or ventilated cages with the applicable cage card.

**b. Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals,**

random-source animals, or both.

Rodents from approved sources are placed directly in rooms according to source and individual investigator. Approved source animals are monitored as part of the Quality Assurance Program and undergo an acclimation period. Rodents from unapproved sources are received on a case-by-case basis based on the information provided by the source on the "Unapproved Sources Facility Data Sheet" regarding that facility's Quality Assurance Program. Processing of an unapproved source order does not proceed until this information is evaluated and approved by a LAM veterinarian. Animals are received and placed in quarantine for 10-30 days for standard testing. Holding periods may be longer depending on test results and subsequent treatment. The decision to release is based on investigator requirements and any additional testing required by the veterinarian. Additional testing may include but is not limited to observation, anal tape test, serology, and histopathology and may require sacrifice of sentinel or quarantine animals if deemed necessary.

Rodents destined for the barrier facility are received as above and quarantined in room (b)(2). The animals are quarantined in this room for a minimum of 6 weeks, pending results of serology and pathology of quality assurance animals. After completion of the quarantine period, the animals are placed in positive pressure IVC units in the barrier colony.

Approved source rabbits and ferrets are placed in rooms with no quarantine period. Animals do undergo an acclimation period.

Pigs received are placed in designated large animal rooms and remain there until used. Animals used in recovery procedures may be housed individually if scientifically or clinically justified, but always have visual and olfactory contact with other animals in the room. Animals are treated for external and internal parasites, if needed. Animals that are housed long term are vaccinated as needed.

**c. Describe the required/recommended stabilization period for each species.**

When there is no requirement for quarantine, investigators should try to provide for a stabilization period to allow physiological, psychological, and nutritional stabilization of the animals before their use. The specific length of time for stabilization will depend on the type and duration of animal transportation, species, and the intended use of the animals. A minimum of 3 days must be provided when animals are to be used to collect scientific data. Non-stabilized animals can be used for acute (terminal) tissue collection, terminal teaching laboratories, or in cases where it is determined that immediate use is the least stressful to the animal and does not compromise the scientific data.

**3. Separation by Health Status and Species [Guide, pp. 111-112]**

- a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

All animals are currently housed by species and status (approved source, unapproved source, barrier, animal biosafety level, protocol-approved housing condition, etc.).

- b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

Only one species is currently housed per room. Possible situations that may require housing multiple species in the same room are to support requirements of an IACUC-approved protocol or severe space limitations (as might happen in a disaster scenario). If multiple species housing was required, animals would be separated as much as possible on opposite sides of the room. Rodents would be housed on separate racks either in microisolator cages or IVC units. Rodent cage changes would occur in a laminar flow hood, which would be disinfected between species

- c. Describe isolation procedures and related facilities for animals.

There is no dedicated isolation area or room. Individual animal rooms can be designated as isolation, if needed, based on animal care processes and restricted access. Ill animals are immediately evaluated by a veterinarian. Animals that show signs of an infectious disease are isolated from healthy animals in the colony. If an entire room of animals is believed to be exposed to an infectious agent, the group is kept intact during the process of diagnosis, treatment, and control.

## **C. Clinical Care and Management** [*Guide*, pp. 112-115]

### **1. Surveillance, Diagnosis, Treatment and Control of Disease** [*Guide*, pp. 112-113]

- a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:
- the observers' training for this responsibility
  - method(s) for reporting observations (written or verbal)
  - method(s) for ensuring that reported cases are appropriately managed in a timely manner.

The veterinary technicians conduct animal health rounds at least once daily. During rounds technicians check for abnormal/ill animals and environmental/facility problems to include feed, water, lights, temperature, and sanitation. When more frequent observations are needed, they are coordinated by a veterinarian. Technicians are trained U.S. Army Veterinary Care Specialists or U.S. Navy surgical technicians, some

of whom are AALAS-certified. All have received adequate training to evaluate the species in use, including shadowed rounds with experienced technicians. Animal caretakers also report animal abnormalities or illnesses to either a veterinary technician or a veterinarian. Any abnormalities are recorded on the daily rounds sheet and may be communicated verbally to a veterinarian. A copy of the completed rounds sheet is given to the NCOIC, VMD for review and then forwarded to the veterinarian for signature. A copy of the rounds sheet is filed in the VMD office. When sick or dead animals are found, a sick call card is completed and the veterinarian and the investigator are immediately notified. On weekends and holidays, the on-call veterinarian is notified when the technician has completed rounds and of any problems detected. Additionally, research staff may report abnormalities directly to LAM technicians or veterinarians.

- b. Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

Animal health and welfare issues are first communicated to researchers by telephone or in-person, if possible. An email will be sent if the staff is unable to reach research staff or as a follow-up to the conversation. Research staff will contact LAM staff in-person, or by telephone or email.

- c. Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

All research animals used at USUHS are purpose-bred animals for research and are purchased from reputable vendors. Prior to approving the shipment of animals from other sources, health reports are requested and reviewed by a veterinarian. Animals ordered from vendors are also accompanied with a current health report.

Pigs on long-term studies receive semi-annual physical exams to include complete blood count and serum chemistries, if needed. A fecal flotation is performed quarterly. Hooves are trimmed as needed. Pigs are weighed monthly and feed is adjusted accordingly. Weights may be checked weekly if necessary. Vaccinations are provided by the vendor. Pigs arrive vaccinated for *Mycoplasma pneumonia*, circovirus, swine influenza virus, *Bordetella bronchiseptica*, *Erysipelothrix rhusiopathiae*, and *Pasturella*.

Ferrets receive semi-annual physical exams and fecal analysis. They receive a distemper vaccine and rabies vaccine annually. Nails are checked monthly and clipped as needed. Ears are checked monthly and cleaned as needed. Animals are weighed monthly.

Rodent sentinels are housed and sampled quarterly. Sentinel animals are placed in each mouse and rat room at the rate of two/70-80 cages of colony animals. The

animals are exposed to room air and dirty bedding retrieved from soiled cages at change outs. Evaluation includes histology, bacteriology, parasitology, and serology.

Rabbits are checked monthly to evaluate teeth and nails and trimmed as necessary. Weights are taken monthly. Rabbits are brushed and/or petted weekly.

Any biologicals that may be used in animals as part of an approved protocol must be tested and verified pathogen free, if applicable, IAW IACUC Policy #23

## **2. Emergency Care [Guide, p. 114]**

- a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

A veterinarian and veterinary technician are on-call 24 hours a day, seven days a week. Contact numbers are posted throughout the facility. On-call schedules are provided to all LAM technicians and veterinarians.

- b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The AV or designee is authorized to provide emergency treatment to animals. An effort to discuss treatment plans with researchers will be made, however, the IO and IACUC have authorized the AV to provide treatment, including euthanasia, to minimize or alleviate pain, distress or suffering of laboratory animals.

## **3. Clinical Record Keeping [Guide, p. 115]**

- a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

All treatments and procedures are recorded in the animal's medical record (large animals) or on the cage card/round sheets (rodents). Permanent records are maintained for rabbits, ferrets, and pigs. The permanent record contains laboratory reports, physical examination forms, weight charts, master problem lists, surgery reports, shipping data, health certificates, and other documentation related to the animal's health history. Medical record entries are annotated using the SOAP format.

- b. Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including

the IACUC/OB has access to the records.

Animal technicians maintain the permanent records for all large animals in Room (b)(2). Daily round sheets are maintained in (b)(2). All veterinary technicians and veterinarians have access to the records.

**c. Describe the role of the Attending Veterinarian in recordkeeping.**

The AV is responsible for the oversight of medical record management and processes to assure all records are accurate and current.

**4. Diagnostic Resources.** Describe available diagnostic methods used in the program including:

**a. In-house diagnostic laboratory capabilities.**

Fecal flotation examinations, tape test examinations, rapid tissue staining (Diff-Qwik), hematocrit

**b. Commercially provided diagnostic laboratory services.**

All required diagnostic testing provided by (b)(4)  
(b)(4) (ADV testing for ferrets)

**c. Necropsy facilities and histopathology capabilities.**

Necropsy service is performed by one of the LAM veterinarians or as needed by an AFRRI veterinary pathologist. Research samples are prepared by the Biomedical Instrumentation Center before being sent to AFRRI for evaluation by a veterinary pathologist. Histopathology samples for sentinel or ill animals are sent to the Joint Pathology Center at the Forest Glen Annex in Silver Spring, MD for processing and evaluation.

**d. Radiology and other imaging capabilities.**

LAM has a (b)(4) Portable C-arm fluoroscope (75KVp, .100Ma) used primarily in Room (b)(2). This equipment is maintained by a service contract. It is available for use as veterinary diagnostic equipment or for IACUC-approved research protocols. Room (b)(2) is the Translation Imaging Facility which houses a CT/PET Scanner. The (b)(4) PET scanner is a small bore (12 cm) with ~1.5 mm spatial resolution and 2D and 3D reconstruction. It is used for functional imaging using 18F-labeled tracers. A (b)(4) Multimodality CT scanner docks to the PET scanner. The CT scanner is small bore (12cm) with a single bed PET to CT and maximum spatial resolution of 40µm. It is expandable to include SPECT imaging (1

mm resolution). A (b)(4) MRI is located G046. It has 660 mT/m gradient strength and a 11.4 cm gradient coil. It contains rat and mouse phased-array coils, 4-8 receiver channels, parallel imaging function and a (b)(4) animal positioning system.

## 5. Drug Storage and Control

### a. Describe the purchase and storage of controlled and non-controlled drugs.

Non-controlled drugs are ordered by the NCOIC of LAM. Controlled drugs are ordered through the USUHS Pharmacy.

Non-controlled drugs are maintained in locked cabinets in (b)(2) with access limited to LAM technicians and veterinarians.

Controlled drugs used by LAM are stored in an approved drug safe located in an access controlled area (Room (b)(2)).

Individual investigators may maintain non-controlled drugs in their laboratories. Each research department has a controlled drug custodian that maintains and dispenses controlled substances to research staff within the department. Schedule II drugs are held in a departmental safe - the safe must be in a room that is locked when no personnel are around. Only small amounts of Schedule II drugs for daily use are provided to investigators who must also hold these in a locked cabinet or refrigerator.

### b. Describe record keeping procedures for controlled substances.

Controlled substances are logged on USUHS form 6049A. Individual log sheets are maintained for each controlled drug. Records are annotated whenever there is a receipt of new drugs, use of drugs, or containers are either emptied or expired. The University Controlled Substances and Alcohol Inventory Board performs an annual review of controlled drug logs and courtesy inspections can be requested at any time.

## D. Surgery [Guide, pp. 115-123]

### 1. Pre-Surgical Planning [Guide, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

All surgical procedures are approved by the IACUC through protocol review. All animal use protocols that require a surgical procedure are required to have a description of pre-surgical (including prepping procedures) and post-surgical care, fasting period, anesthesia,



post-surgical analgesics, and post-procedure observation. The investigator is mandated to discuss all surgical-related procedures with a LAM veterinarian during the protocol pre-review process prior to IACUC submission. The PI must ensure that the personnel performing the surgical procedures are appropriately trained.

Pre-surgical planning includes input from all members of the surgical team, including the surgeon, anesthetist, veterinarian, surgical technicians, veterinary technicians, and investigator. Non-emergency surgeries are scheduled at least seven calendar days in advance. When a request for surgery to support a research or training protocol is received, the VSD surgical coordinator will review the requested procedures. Following this review, necessary equipment and supplies are gathered or procured. Investigators will discuss equipment and supply needs with LAM staff sufficiently early to allow acquisition of the equipment and/or supplies. VSD personnel will ensure the investigator completes the "Nothing Per Os" request (LAM form 488) when required no later than noon on the day prior to surgery.

## 2. Surgical Facilities [Guide, pp. 116-117, 144-145]

List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:

- the type of species (including rodents, fish, agricultural species, etc.)
- nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
- the amount of use [heavy (daily), moderate (weekly), or light]
- major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
- facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
- construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

*Note:* If preferred, the information requested in this section may be provided in Table.

Large animal (e.g. rabbits, ferrets, and agricultural species) surgeries occur in rooms (b)(2) of the CAF. Room (b)(2) is used for both non-survival and survival procedures; use of this room is moderate. Room (b)(2) is the primary OR used for major survival surgeries; use of this room is light and occurs periodically. Rooms (b)(2) and (b)(2) are not currently being used for surgical procedures due to current low demand. However, these rooms are available for surgical procedures.

Non-survival surgeries for training courses can be performed in room (b)(2). Non-survival surgeries performed under approved protocols for the surgery department of USUHS may be performed in LAM or in room (b)(2).

Rodent surgeries to include survival and non-survival procedures are conducted in procedure rooms within the CAF or in PI laboratories, which are inspected and approved by the IACUC.

### 3. Surgical Procedures [*Guide*, pp. 117-118]

- a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

Major survival surgery penetrates and exposes a body cavity, produces substantial impairment or physical or physiologic functions, or involves extensive tissue dissection or transection. Major survival procedures include but are not limited to laparotomy, thoracotomy, joint replacement, and limb amputation. Laparoscopic surgeries and some procedures associated with neuroscience research (e.g., craniotomy, neurectomy) may be classified as major surgery depending on their impact on the animal.

Minor survival surgery does not expose a body cavity and causes little or no physical impairment. Examples include wound suturing, peripheral vessel cannulation, percutaneous biopsy, and most procedures routinely done on an "outpatient" basis in veterinary clinical practice.

- b. How is non-survival surgery defined?

Non-survival is any surgical procedure performed on an anesthetized animal after which the animal is euthanized without being allowed to recover from anesthesia and regain consciousness.

### 4. Aseptic Technique [*Guide*, pp. 118-119]

- a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

Aseptic technique includes wearing of sterile surgical gloves, gown, cap, shoe covers and face mask; use of sterile instruments and supplies; a five minute hand and forearm surgeon scrub; and aseptic preparation of the surgical field. Preparation of the surgical field for non-rodent species includes clipping hair from the incision site and performing a series of three iterations of scrubbing with a surgical soap/disinfecting solution followed by an alcohol wipe and the use of sterile drapes. Aseptic technique must be used on all animals that undergo survival surgery. Survival surgery on all non-rodents must be conducted only in dedicated surgical suites. Survival surgery on rodents does not require a special facility, but must be performed on an easily sanitized surface located in a low traffic area. Surgical instruments for rodent surgery must be sterile initially, but then can be re-sterilized for subsequent surgeries being performed in succession by use of either a glass bead sterilizer or cold sterilizer. When a glass

bead sterilizer is used, the instruments must be allowed to cool prior to use. When a cold sterilizer is used, the instruments must be rinsed first with sterile saline before they are applied to any tissue. Sterile surgical gloves, a lab coat, and a face mask are the minimum PPE requirements for performing rodent surgery.

- b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

All surgical instruments are rinsed and then placed in an enzyme solution to soak for 3 minutes. They are then placed in the washer for steam cleaning. Once the washer cycle is complete, the instruments are transported to the sterile processing room, and placed in appropriate packs. A steam sterilization indicator strip is placed inside each pack. The pack is then double wrapped in sterilizing material. The wrapped instrument packs are closed with autoclave tape, which changes color when the appropriate temperature is reached. Packs are placed in a steam sterilizer for 30 minutes where temperatures reach 270°F for 10 minutes. The sterile surgical gowns and other protective clothing used are all of the disposable type and discarded after use.

- c. Describe methods for instrument re-sterilization between serial surgeries.

Surgical instruments for rodent surgery must be sterile initially, but then can be re-sterilized for subsequent surgeries being performed in succession by use of either a glass bead sterilizer or cold sterilizer. When a glass bead sterilizer is used, the instruments must be allowed to cool prior to use. When a cold sterilizer is used, the instruments must be rinsed first with sterile saline before they are applied to any tissue.

- d. Indicate how effectiveness of sterilization is monitored.

The autoclave provides a printed tape documentation of the temperature and pressure achieved. This time exposure is consistent with human sterilizing procedures. Each week, a <sup>(b)(4)</sup> (also known as <sup>(b)(4)</sup> Biological Indicator Test Pack is run through the sterilizer to ensure sterilization effectiveness. Weekly Bowie-Dick tests are also performed to ensure appropriate air removal from the autoclave during operation.

- e. Describe surgical support functions provided by the program to investigators.

VSD provides all surgical support to the dedicated non-rodent surgical suites. VSD staff is responsible for cleaning, straightening and re-supplying the surgery suites as needed after each use in preparation for the next surgery. This includes spraying and wiping down all surfaces with <sup>(b)(4)</sup> and mopping the floor. VSD monitors the supply of sterile instruments, PPE, equipment, anesthetic, and O2 supply to assure sufficient quantities are available. VSD provides patient preparation, anesthesia administration, intraoperative monitoring, and post-operative recovery and care.

Within the CAF, procedure rooms are available for rodent surgeries. LAM staff provides general cleaning of these rooms but the PI is responsible for cleaning the area after use. Supplying equipment and surgery items for the particular rodent surgeries is the responsibility of each investigator. Rodent surgeries conducted in PI laboratories are not supported by LAM.

**5. Intraoperative Monitoring** [*Guide*, p. 119]

Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

All non-rodent species' surgical procedures (survival or non-survival) are monitored by LAM staff. This includes monitoring temperature, respiration rate, and heart rate at a minimum. Other parameters such as O<sub>2</sub> saturation, CO<sub>2</sub>, EKG and blood pressure are monitored depending on the complexity of the surgical procedure. All anesthesia monitoring is recorded on an anesthesia monitoring record and placed in the animal's medical record. A surgery report, which provides a detailed description of the surgical procedure, is also included in the medical record.

All rodent surgeries (survival or non-survival) are monitored by research staff. At minimum animals are monitored for depth of anesthesia (toe pinch or corneal reflex). More extensive monitoring may be performed depending on the complexity of the surgical procedure. Surgical procedure descriptions, anesthesia monitoring records, and post-operative recovery monitoring records are maintained by the investigative staff.

**6. Postoperative Care** [*Guide*, pp. 119-120]

Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

An environmentally-controlled intensive care unit is available in Room (b)(2) for animals undergoing survival surgery. The AV and the PI share responsibility for oversight of post-operative care. The responsibility for providing post-operative care is shared between the research and LAM staff. Monitoring guidelines and treatments are determined by the PI in consultation with the Chief, VSD and incorporated into an IACUC-approved protocol. For all species, post-operative analgesia is available as described in the research protocol unless specifically prohibited and soundly justified in the IACUC-approved protocol. VSD staff is responsible for monitoring the animal until it is recovered from anesthesia (conscious, able to swallow, able to achieve a sternal resting position). Beginning the first day post-operatively or when an assessment is made that the animal has recovered, it will be returned to a cage in the CAF. The animal is monitored at least twice daily by the research staff and/or LAM technicians to assess health (e.g. appetite, water intake, incision site, urination, defecation). Any post-surgical treatment (e.g. antibiotics, analgesics, bandage changes, etc.) is administered in accordance with the approved protocol by the PI, research staff, or LAM personnel. Pertinent information on the surgical procedure is

documented in the surgery report. The surgery report and anesthesia report are filed in the animal's medical record.

Research staff is responsible providing post-operative care and record keeping for all rodent survival surgeries. Post-operative care monitoring is documented in investigator notes and/or on cage cards.

#### **E. Pain and Distress** [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

Pain and distress are assessed and categorized in accordance with the Animal Welfare Regulations and IACUC policy. The categories are included in the DOD animal protocol template as no or minimal pain or distress (column C), alleviated pain or distress (column D), and unalleviated pain or distress (column E). The PI in consultation with a LAM veterinarian is initially responsible for assessing which is the appropriate category. The IACUC approves the final pain or distress category after reviewing the protocol. On-going assessment is performed by each investigator and the LAM staff. Animals are monitored for proper post-operative recovery, including the use of analgesics. The annual protocol review form also requires the PI to report any changes in pain category or morbidity/mortality during the course of the study.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

All investigators must complete the (b)(2) offered by LAM personnel. Documentation of completion is provided to the IACUC office. Investigators proposing to work with mice or rats are also (b)(2) presented by LAM unless prior experience or training can be demonstrated to the IACUC. LAM can also provide species- or procedural-specific training on a case-by-case basis.

#### **F. Anesthesia and Analgesia** [*Guide*, pp. 121-123]

1. List the agents used for each species.

*Note:* If preferred, this information may be provided in Table or additional Appendix.

Anesthesia and analgesia agents may change with different procedures; however they all must be reviewed and approved by a LAM veterinarian and the IACUC. All dosages and routes of administration are listed in the respective protocols. The following list is not completely inclusive of all possible agents that may be used for anesthesia, analgesia, and tranquilization.

Rabbit: Ketamine/Xylazine, Isoflurane, Sevoflurane, Dexmedetomidine, Pentobarbital, Burprenorphine, Acetaminophen, Meloxicam, Carprofen, Lidocaine or Bupivacaine

Rodent: Ketamine/Xylazine, Pentobarbital, Isoflurane, Burprenorphine, Acetaminophen, Meloxicam, Carprofen, Lidocaine or Bupivacaine

Swine: Ketamine/Xylazine, Isoflurane, Pentobarbital, Telazol/Xylazine, Burprenorphine, Fentanyl, Acetaminophen, Meloxicam, Carprofen, Lidocaine or Bupivacaine

Ferrets: Ketamine/Xylazine, Isoflurane, Burprenorphine, Acetaminophen, Meloxicam, Carprofen, Lidocaine or Bupivacaine

Additionally, the IACUC may determine on a case-by-case basis that the provision of therapeutics and/or palliative care is sufficient to alleviate pain/distress. Appropriate nursing support may include a quiet, darkened recovery or resting place, timely wound or bandage maintenance, increased ambient warmth and a soft resting surface, rehydration with oral or parenteral fluids, and a return to normal feeding through the use of highly palatable foods or treats. Also, the treatment of distress caused by stressors other than pain (such as providing additional bedding, more easily reachable food or water, fluid therapy, or other improvements in comfort and homeostasis) are frequently overlooked forms of refining animal use.

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

During the protocol review process, a LAM veterinarian evaluates anesthesia and analgesia methods and makes recommendations to the investigator prior to IACUC approval. During the course of an ongoing protocol, if it becomes apparent that an approved method of providing analgesia or anesthesia is not effective or feasible, a LAM veterinarian will consult with the PI regarding use of a different regimen. LAM veterinarians are available at all times for consultation and are routinely contacted by investigators to discuss experimental procedures.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

Anesthetic and analgesic monitoring is performed by the veterinary staff and PI and their research staff. During protocol development, the PI and a LAM veterinarian discuss monitoring, such as species-specific clinical signs/anesthesia depth response in relation to the use of anesthetics and analgesics.

LAM technicians and veterinarians monitor surgeries performed in the LAM surgery suite. The PI's research staff and/or LAM staff monitor the need for post-operative analgesics. For animals requiring post-operative analgesia, annotations are made on the SF600, which is kept in the animal's medical record, or on a yellow "sick call" card or in the PI's lab records. For procedures that occur outside the CAF, the PI and their research staff are responsible for monitoring the use of anesthetics and analgesics. The IACUC verifies proper use of anesthetic agents via semi-annual inspections of the University's animal-use laboratories.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

LAM veterinarians review the proposed use of neuromuscular blocking agents during the protocol pre-review process. The IACUC reviews the use of neuromuscular blocking agents during the protocol review process. The use of neuromuscular blocking agents without analgesia or anesthesia is prohibited.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

Anesthesia machine vaporizers are serviced annually to assure proper function. Stickers are placed on the vaporizers to indicate the date last serviced. Anesthesia machines are leak-tested prior to every use. When used, charcoal canisters are replaced after 12 hours of use or after an increase of 50 grams from the base weight to ensure waste gases are scavenged. Soda lime canisters are labeled with the date last changed and will be changed when the color begins to change to purple.

#### **G. Euthanasia [Guide, pp. 123-124]**

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
  - consideration of species, age, condition (e.g., gestational period, or neonatal) and
  - location(s) for the conduct of the procedure.

*Note:* If preferred, this information may be provided in Table or additional Appendix.

Methods of euthanasia used at USUHS are in accordance with the 2013 AVMA Guidelines for the Euthanasia of Animals. Euthanasia occurs in dedicated procedure rooms or laboratories, which are evaluated by the IACUC during semi-annual program review and facility inspections. Euthanasia methods are performed as described in IACUC-approved protocols. Research personnel that perform euthanasia have been appropriately trained and approved by the IACUC. Consideration of species, age, condition, and location are evaluated and approved during the protocol review process with input from LAM veterinarians. Secondary physical means of euthanasia are required to ensure death.

The following methods are approved and routine methods of euthanizing animals:

Rodents: Barbiturates, CO<sub>2</sub> (compressed gas cylinder only), cervical dislocation or decapitation (must be scientifically justified and approved by IACUC), exsanguination under anesthesia, microwave fixation

Neonatal rodents: Barbiturates, decapitation, CO<sub>2</sub> with prolonged exposure times

Rabbits: Barbiturates, exsanguination under anesthesia

Swine: Barbiturates

Ferrets: Barbiturates

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

Pressurized tanks dispensing CO<sub>2</sub> must always be available through an exchange program through a local vendor. Flow meters must be attached to CO<sub>2</sub> cylinders. Isoflurane vaporizers are serviced and calibrated annually. Scissors and guillotines for decapitation are required to be cleaned and sharpened.

3. Describe the methods used to confirm death of an animal.

Methods used to confirm death are as follows:

Rodents

Bilateral pneumothorax

Cervical dislocation

Removal of major organs

Decapitation

Exsanguination under anesthesia

Large Animals

Bilateral pneumothorax

Removal of major organs

Exsanguination under anesthesia

Cessation of auscultable heart and respiration rate after 5 minutes following euthanasia

#### IV. Physical Plant [Guide, pp. 133-155]



### A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

The University is located in Bethesda, MD on the grounds of the Walter Reed National Military Medical Center. All of the animal facilities are on the University's campus which consists of five buildings (designated A, B, C, D, and E) (b)(2)  
(b)(2)  
(b)(2) Four satellite animal rooms (b)(2)  
(b)(2) are located in (b)(2) on three different floors next to the service elevators and in close proximity to research laboratories.

### B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas

incorporating fewer or additional security features than the general features described.

7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

The University is located in Bethesda, MD on the grounds of the Walter Reed National Military Medical Center. All of the animal facilities are on the University's campus which consists of five buildings (designated A, B, C, D, and E) and a large underground floor (designated Ground Floor) that connects with all the University's buildings through a series of corridors and elevators. The CAF is located on the Ground Floor. The CAF and satellite rooms are easily accessed by all research staff and are in close proximity to all laboratories.

(b)(2)

(b)(2)

Exceptions to this access restriction are made to allow for support of specified research requirements. These special requirement requests are reviewed on a case-by-case basis and must be approved by the Director, LAM. (b)(2)

(b)(2)

Animals can be moved to and from the laboratories using the corridors and elevators without exiting the building. The conventional animal housing area of the CAF uses a to- and fro-footpath with common use corridors. The rodent barrier facility encompasses one complete block of animal rooms with a corridor on each side and utilizes a clean/dirty corridor system.

All corridors and animal rooms within the animal facility have a smooth, monolithic, seamless, epoxy aggregate floor system with integral coving. Walls are Concrete Masonry Unit construction with epoxy paint coating. Ceilings in corridors, animal, procedure, and cage wash areas are made of epoxy-coated concrete or moisture resistant plasterboard (b)(2) cage wash). Continuous, stainless steel bumpers are mounted nine inches above the floor level to protect walls. Doors are constructed of epoxy-coated metal.

Engineering controls for hazardous agents include once-through air handling system with specific animal rooms at negative pressure relative to corridors and the use of biosafety cabinets, chemical fume hoods, and laminar flow work stations.

There are no exterior windows located in any CAF animal rooms. (b)(2)

(b)(2)

Flammable items are stored in a fire safety cabinet located a storage room (b)(2)  
Disinfectants and cleaning supplies are stored in (b)(2) on pallets that provide secondary containment or in a secondary containment device on regular pallets/shelves.

### C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

Rooms outside the central animal facility that hold animals for longer than 12 hours are defined as satellite areas in accordance with IACUC Policy #031. Four permanent satellite animal rooms (b)(2) are located in (b)(2) on three different floors next to the service elevators and in close proximity to research laboratories.

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

The four satellite rooms are managed by the Director, LAM, who directly reports to the Assistant Vice President for Technology, Research, and Innovation. The Chiefs of VMD and VSD provide daily management of their respective areas. The Chief, AHD provides daily management for all husbandry activities in the CAF and satellite rooms. The IACUC provides programmatic oversight to all rooms housing or using animals. Labs used as satellite rooms must be described in the protocol and include scientific justification, duration of housing, care and monitoring procedures. Labs must maintain a housing log and follow LAM husbandry SOPs unless specific exceptions are described within the protocol. Specific details are outlined in IACUC policy #031.

#### D. Emergency Power and Life Support Systems

Note: Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

##### 1. Power [Guide, p. 141]

For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:

- Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
- History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

There are two (b)(4) priority power lines supplying the University. During normal operations, (b)(2)

(b)(2)

(b)(2) to the University fail, two back-up generators are present to supply power to the CAF. These generators will come on immediately in the event of a power failure. The generators are capable of running for 3 days before refueling is necessary. The generators are tested monthly. The CAF has never experienced a power outage greater than one minute in duration.

##### 2. Other System Malfunctions. If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

There have been no animal mortality or health problems associated with power failures nor other system malfunctions.

#### E. Other Facilities [Guide, pp. 144, 150]

##### 1. Other Animal Use Facilities [Guide, pp. 146-150]

Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

LAM has a (b)(2) 2 Portable C-arm fluoroscope (75KVp, .100Ma) used primarily in Room (b)(2). The Translational Imaging Facility contains (room (b)(2) and

room (b)(2) (b)(4) Positron Emission Tomography (PET) Scanner – live animal imaging for neuroscience and other applications; (b)(4) Multimodality Computed Tomography (CT) Scanner – live animal imaging for neuroscience and other applications; and (b)(4) Magnetic Resonance Imaging (MRI) – live animal imaging for neuroscience and other applications. (b)(2) contains a hypobaric chamber. Imaging equipment is disinfected with MB-10 prior to and following use.

**2. Other Animal Program Support Facilities**

Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

N/A

## Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

Abbreviation/Acronym	Definition
USUHS	Uniformed Services University of the Health Sciences
IAW	In accordance with
DOD	Department of Defense
LAM	Center for Laboratory Animal Medicine
IACUC	Institutional Animal Care and Use Committee
USUHSINST	USUHS Instruction (University policy)
AHD	Animal Husbandry Division
VSD	Veterinary Surgery Division
VMD	Veterinary Medicine Division
ACUP	Animal Care and Use Program
NCOIC	Non-Commissioned Officer in Charge
EHOS	Environmental Health and Occupational Safety
CNRM	Center for Neuroscience and Regenerative Medicine
CNS	Central Nervous System
TBI	Traumatic Brain Injury
AFRRI	Armed Forces Radiobiology Research Institute
IO	Institutional Official
HM(#)	(Hospital Corpsman) Navy Military Rank, with lower number equaling higher rank
PV2	Army Private
SPC	Army Specialist
SGT	Army Sergeant
SSG	Army Staff Sergeant
SFC	Army Sergeant First Class
MAJ	Army Major
COL	Army Colonel
IBC	Institutional Biosafety Committee
IHE	Industrial Hygiene and Environmental
HIPAA	Health Insurance Portability and Accountability Act
WRNNMC	Walter Reed National Military Medical Center

## Appendix 1: Glossary of Abbreviations and Acronyms

BMBL	Biosafety in Biomedical Laboratories, 5 <sup>th</sup> edition
SOP	Standard Operating Procedure
PPE	Personal Protective Equipment
MSDS	Material Safety Data Sheets
CAF	Central Animal Facility
FCR	Full Committee Review
DMR	Designated Member Review
ACURO	US Army Animal Care and Use Review Office
(b)(4)	Area Power Provider

## Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

Animal Housing and Support Sites						
Location (building, site, farm name, etc. <sup>a</sup> )	Distance from main facility <sup>b</sup>	Approx. ft <sup>2</sup> , m <sup>2</sup> , or acreage for animal housing	Approx. ft <sup>2</sup> , m <sup>2</sup> , or acreage for support or procedures	Species housed	Approx. Daily Animal Census by species	Person in charge of site
Central Animal Facility	N/A	11,939 sq. ft.	28,273 sq. ft.	Mice	5,000	(b)(6)
				Rats	213	
				Rabbits	5	
				Gerbils	27	
				Ferrets	20	
				Pigs	2	
				Opossum	22	
				Mouse	75	
				Gerbil	27	
(b)(2)						

Totals:		
	12,758	N/A
Total animal housing and support space:		
	12,758 ft <sup>2</sup>	
	(please specify ft <sup>2</sup> or m <sup>2</sup> )	

<sup>a</sup>Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.

<sup>b</sup>Campus or site map(s) may also be provided in lieu of this information.



## **Appendix 3: Line Drawings**

Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5" x 11" or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.

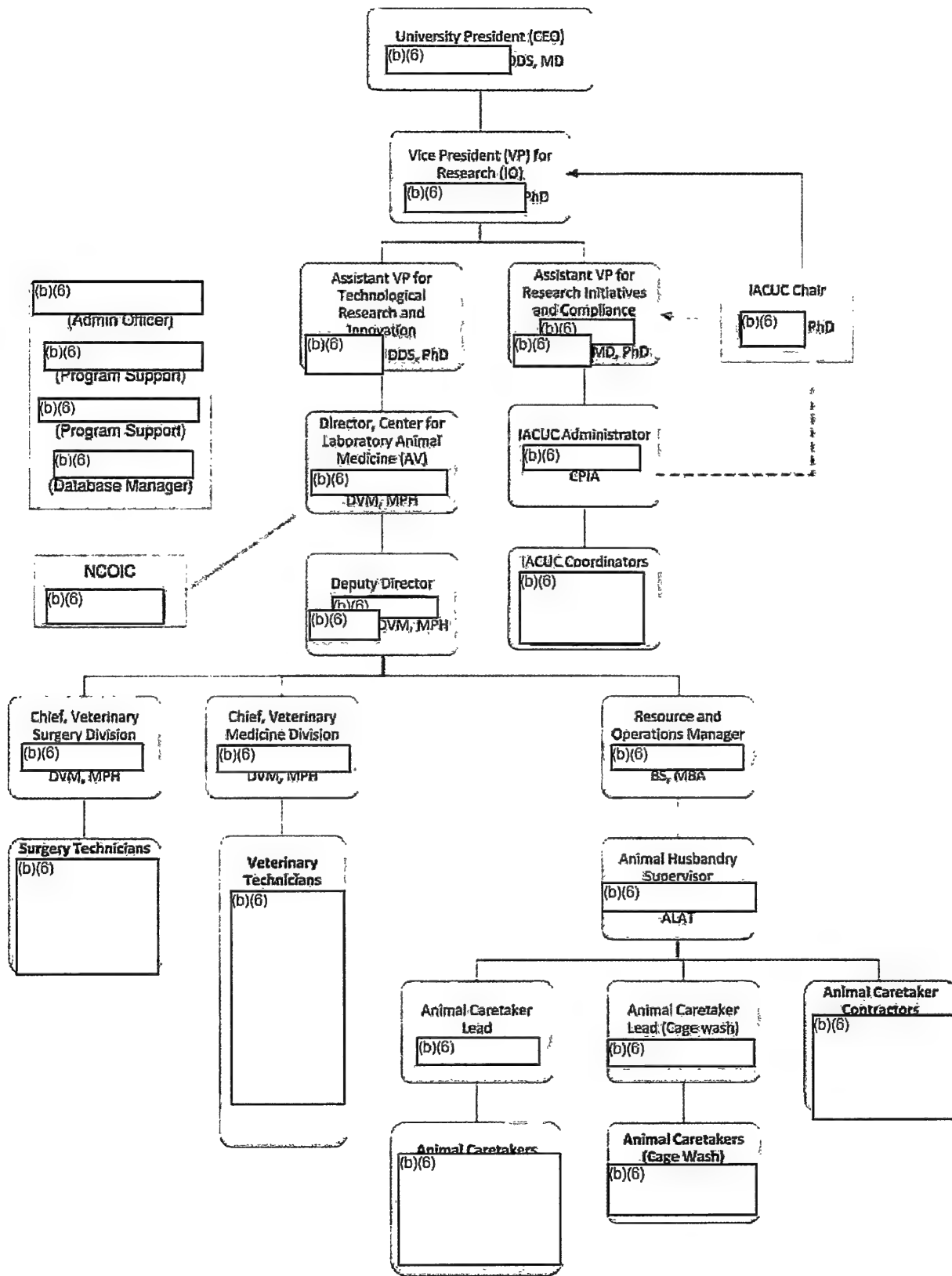
## **Appendix 3: Line Drawings**

**SEE ATTACHMENT FOR DETAILS**

## **Appendix 4: Organizational Chart(s)**

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.

## Appendix 4: Organizational Chart(s)



## Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chaining or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

IACUC/OB Number	Principal Investigator	Species	Total Number of Animals Approved	Pain Distress & Category (1)	Special Considerations (use checkmark if applicable)	MSS (3)	FFR (4)	PR (5)	HAU (6)	NCA (7)
(b)(2)	(b)(6)	Rat	212	C, D, E	SS2					NCA (7)
(b)(2)	(b)(6)	Rat	108	C, D						LAM, (b)(2)

[illegible]

## Appendix 5: Animal Usage

(b)(2)	(b)(6)	Mice - multi	4032	C, D					Yes	(b)(2) (b)(2) LAM, CNRM pre-clinical
		Mice	216	C, D					Yes	(b)(2) LAM.
		Mouse	576	Breeding						
		Rats	2104	C, E					Yes	(b)(2) LAM, (b)(2)
		Mice	792	C, D						(b)(2) LAM

[illegible]



## 2

(b)(2)

# Appendix 5: Animal Usage

(b)(2)	(b)(6)		Mice	2736	C								LAM
			Mice	2700	C, D								LAM
			Mice	2592	C								LAM
			Mice	960	D	Yes						(b)(2)	LAM
			Mice	26	D							LAM, (b)(2)	(b)(2)

[illegible]

[illegible]

(b)(2)	(b)(6)	Mice	1464	C, D					Yes	LAM	(b)(2)
		Mice	10	C, D					Yes	LAM	
		Mice	1680	C, D			Yes			LAM	
		Rats, Mice	1418	C, D						LAM	
		Rats, Mice	3976	B, C						LAM	
		Mice	850	E				Yes	Yes	LAM	

(b)(2)								Rats	340	D, E			Yes	LAM, [REDACTED]
								Mice, Rat	2480	B, C, D, E				LAM, [REDACTED] [REDACTED]
								Mice	2700	B, C, D				LAM
								Mice, Rat	2284	B, C, D, E				LAM, [REDACTED] [REDACTED]
								Mice, Rat	3200	C, D				[REDACTED] LAM
								Mice	146	C				LAM

## Appendix 5: Animal Usage

(b)(2)	(b)(6)	Monodelphis Domestica	190	B	Yes						LAM
		Mice	1216	B, C							LAM
		Mice	102	C							(b)(2)
		Monodelphis Domestica	82	C	Yes						(b)(2)
		Mice	324	C							LAM
		Mice	723	D	Yes						LAM

## Appendix 5: Animal Usage

(b)(2)										(b)(6)									
		</																	



[illegible]

(b)(2)		(b)(6)	Mice	36	C					LAM
			Mice	840	C, E					LAM
			Mice	138	B, C	Yes				LAM
			Mice	604	C, D					LAM
			Mice	1554	B, C					LAM
			Mice	126	C		Yes			(b)(2)
			Mice	180	C					LAM

[illegible]

# Appendix 5: Animal Usage

(b)(2)	(b)(6)	Rats	100	D						LAM
		Rats	75	C, E		Yes				LAM
		Rats	200	C, E		Yes				(b)(6) LAM
		Mice	30	C						LAM
		Mice	309	B	Yes					LAM

[illegible]

# Appendix 5: Animal Usage

(b)(2)	(b)(6)	Mice, Gerbils	6900	C, D	Yes	Yes	(b)(2)
(b)(2)	(b)(6)	Mice	2922	E	Yes		
(b)(2)	(b)(6)	Mice	652	C	Yes		

## Appendix 5: Animal Usage

(b)(2)	(b)(6)		Jirds	864	C					Yes	(b)(2)
			Mice	2849	C, D						procedure room (b)(2)
			Mice	183	C, E						LAM, (b)(2) (b)(2)
			Ferret	125	C					Yes	(b)(2)

## Appendix 5: Animal Usage

(b)(2)	(b)(6)	Mice	11223	C, E			Yes	(b)(2)
		Mice	11187	C, E				
		Mice	4695	C, D		Yes		
LAM								
(b)(2)	(b)(6)	mice	6702	Breeding				(b)(2)
		Mice	1698	C, D			Yes	
		Mice	1116	C, D			Yes	



[illegible]

# Appendix 5: Animal Usage

(b)(2)	(b)(6)	Rat	158	D									(b)(2) LAM, offsite
													(b)(2) LAM
		Rat	68	D	Yes								
		pig	360	D				Yes					LAM
		Mice	15	D									LAM
		Mice	840	D	Yes								(b)(2)

[illegible]

## Appendix 5: Animal Usage

(b)(2)	(b)(6)	Mice	255	C							LAM
		Mice	144	E							LAM
		mice	512	C, E						Yes	LAM
		mice	184	D, E						Yes	LAM

# Appendix 5: Animal Usage

(b)(2)	(b)(6)									
		mice	480	C, E					Yes	LAM
		Mice	2132	C					Yes	LAM, (b)(2)
		Mice	1375	C					Yes	LAM
(b)(2)		Mice	618	C, E					Yes	LAM
		Mice	4725	B, C				Yes		LAM

[illegible]

[illegible]

(b)(2)		(b)(6)	Mice	1344	B, C						LAM
			Rats, Mice	3344	B, C, D, E				Yes	(b)(2)	
			Mice	513	C						LAM
			Mice	732	B, C						LAM
			Rat	1298	C, D			Yes		(b)(2)	
			Mice, Rats	2924	C, D					(b)(2)	LAM



## Appendix 5: Animal Usage

(b)(2)	(b)(6)		Mice	970	C, E						LAM
			mice	2950	C, D, E						LAM
			Mice	1273	B, C						LAM
			Rat	240	C, E				Yes		LAM, (b)(2) (b)(2)
			Rats	280	D, E			Yes			LAM

## Appendix 5: Animal Usage

(b)(2)	(b)(6)		Rats	60	C, D							LAM
			Rats	702	B, C, E	Yes			Yes			LAM, USUHS B
			Rats	95	C, D				Yes			LAM
			Mice, Rats, Ferrets	132	D							CNRM, (b)(2)
			Rat	40	D	Yes						(b)(2) LAM, CNRM

(b)(2)	(b)(6)	Mice	621	C, D, E				Yes	A, LAM
		Pig	102	D					ATL
		Rats	70	D		Yes		(b)(2)	LAM
		Mice	640	D					LAM
		Mice	5962	B, C		Yes			LAM
		Mice	608	D					LAM

## Appendix 5: Animal Usage

(b)(2)	(b)(6)	Mice	5000	C, D							LAM
		Rat	540	D							LAM

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.

- (2) Survival Surgery (SS)
- (3) Multiple Survival Surgery (MSS)
- (4) Food or Fluid Regulation (FFR)
- (5) Prolonged Restraint (PR)
- (6) Hazardous Agent Use (HAU)
- (7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

Pain/Distress Classification is in accordance with corresponding USDA categories.

Appendix 5: Animal Usage

In the Table below, provide an approximate annual usage for all species:

Animal Type or Species	Approximate Annual Use	Animal Type or Species	Approximate Annual Use
Ferret	150	Opossum	55
Gerbil	45	Pig	70
Mouse	24,000	Rabbit	10
Rat	2,800		

## Appendix 6: Personnel Medical Evaluation Form

Provide a **blank** copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).

## Appendix 6: Personnel Medical Evaluation Form

### USUHS

#### ANIMAL EXPOSURE SURVEILLANCE PROGRAM (AESP)

##### I. Health Hazard History

(circle "y" or "n")

I anticipate occupational exposure to animals, their viable tissues, body fluids or wastes: y n  
(COMPLETE AND SUBMIT FORM ONLY IF ANSWER IS "y".)

My anticipated exposure is best described by the following categories: (circle risk category)

Risk Category 1:	rodents, rabbits, aquatics
Risk Category 2:	carnivores (cats, dogs), livestock (goats, sheep, cattle, pigs), ferrets, all other animals except non-human primates
Risk Category 3:	nonhuman primates

Please describe any prior occupational exposure to animals:

## Appendix 6: Personnel Medical Evaluation Form

### ALLERGIES:

History of animal allergies	y	n
History of asthma, allergic sinusitis, allergic rhinitis	y	n
History of allergic rashes	y	n
Family history of same	y	n
Allergy to eggs, neomycin	y	n
Sensitivity to latex products	y	n

### MEDICATIONS:

Chronic use of antihistamines, decongestants	y	n
Antibiotics	y	n
Steroids	y	n
Anti-neoplastic agents/ immuno-suppressive agents	y	n
Anti-epileptic or anti-convulsive medications	y	n

### IMMUNIZATION HISTORY:

Any objections to receiving immunizations?	y	n
Any history of adverse reactions to immunizations?	y	n
Any immune disease?	y	n



## Appendix 6: Personnel Medical Evaluation Form

Any current fever or infection?	y	n
Received immune globulin in the past three months?	y	n
Are you pregnant or anticipating pregnancy?	y	n
Tetanus immunization in past 10 years?	y	n
		_____ date
Hepatitis B immunization series?	y	n
		_____ date
Rabies immunization series?	y	n
		_____ date

### MEDICAL HISTORY:

Low Back Problems	y	n
Seizures	y	n
Skin Rashes	y	n
Hearing Loss	y	n
Susceptibility to lung infections	y	n
Asthma	y	n
Smoking	y	n
Neurological disease	y	n
Liver disease (hepatitis)	y	n
Kidney disease	y	n
Valvular or Congenital heart disease	y	n

History of MI or angina	y	n
Immune-suppressive disease (including HIV)	y	n
Diabetes Mellitus	y	n
For workers exposed to Non-human primates		
Date of last TB screening	_____	
For TB converters, date of last Chest x-ray	_____	
Rubeola (measles) titer or vaccination	_____	

<div>Last Name</div>	<div>First Name</div>	<div>Social Security Number</div>
<div>Date of Birth</div>	<div>Department</div>	<div>Work Phone Number</div>
<div>SIGNATURE</div>	<div></div>	<div>DATE</div>

## 135 8/16

Appendix 6: Personnel Medical Evaluation Form

SIGNATURE

DATE

OCCUPATIONAL HEALTH STAFF

Program Updated 26 July 1999

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974

1. AUTHORITY: Sections 133, 1071-87, 3012, 5031 and 8012, title 10, United States Code and Executive Order 9397.
2. Principal and Routine Purposes: To provide, plan and coordinate medical surveillance services and provide medical certification for  
USUHS and AFRR1 Animal Handlers consistent with LAM policy.
3. Mandatory or Voluntary Disclosure: Failure to provide information may result in denied AESP certification. AESP certification is  
required to gain entry into the LAM Department and to handle animals occupationally.

## Appendix 7: IACUC/OB Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

Members	Dept	Primary	Category	Alternate for
(b)(6) Ph.D.	PHA	X	Chair/Scientist	
(b)(6) DVM, MPH	LAM	X	Attending Vet (AV)	
(b)(6) DVM, MPH	LAM		Scientist	AV/Any Scientist
(b)(6) DVM, MPH	LAM		Scientist	AV/Any Scientist
(b)(6) DVM, MPH	LAM		Scientist	AV/Any Scientist
(b)(6) D.D.S., Ph.D.	APG	X	Scientist	
(b)(6) Ph.D.	PMB		Scientist	Any Scientist
(b)(6) Ph.D.	MEM	X	Scientist	
(b)(6) Ph.D., BVSc	MIC		Scientist	Any Scientist
(b)(6) Ph.D.	APG	X	Scientist	
(b)(6) RP2	BDE		Nonscientist	Nonscientist
(b)(6) Ph.D., RD	MEM		Scientist	Any Scientist
(b)(6) Ph.D.	MIC	X	Scientist	
(b)(6) Ph.D.	MED		Scientist	Any Scientist
(b)(6)	NIH	X	Nonaffiliated	Nonaffiliated
(b)(6) IM.Div	MEM	X	Nonscientist	
(b)(6) Ph.D.	PED	X	Scientist	
(b)(6) Ph.D., BVSc	MIC	X	Scientist	
(b)(6) M.D.	SUR		Scientist	Any Scientist
(b)(6) Ph.D.	MED	X	Scientist	
(b)(6) Ph.D.	APG	X	Scientist	

## Appendix 7: IACUC/OB Membership Roster

(b)(6)	DrPH	PMB	X	Scientist	
(b)(6)		LRC	X	Nonscientist	
	Ph.D.	ANE	X	Scientist	
(b)(6)	Ph.D.	PHA		Scientist	Any Scientist
	M.D.	PAT	X	Scientist	
<b>IACUC STAFF</b>					
(b)(6)		ORC	Nonvoting	Staff	
		ORC	Nonvoting	Staff	
		ORC	Nonvoting	Staff	
		ORC	Nonvoting	Staff	

## **Appendix 8: IACUC/OB Minutes**

Please provide the latest two Minutes of the IACUC/OB meetings.

PROVIDED AS A SEPARATE ATTACHMENT.

## Appendix 9: IACUC/OB Protocol Form

Please attach a **blank** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.

PROVIDED AS A SEPARATE ATTACHMENT.

## **Appendix 10: IACUC/OB Periodic Report**

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.

PROVIDED AS A SEPARATE ATTACHMENT.



## Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, *including all satellite facilities*. Include *all animal holding rooms* (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

<b>Location/Building/Facility:</b>
------------------------------------

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, etc.)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

<b>Air handling unit #16 A and B</b>
--------------------------------------

**The source:** The bulk of the LAM central animal facility is serviced by air handling units (AHUs) #16A and 16B. AHU 16A and 16B were constructed in 2004 as part of Phase 10 of the HVAC Repairs/Replacement project. The two units are 100% outside air (OA), constant volume, and share a common header.

**Treatment of air:** pre-filters are MERV 8 (95%) American Air filter Megapleat; Final filter MERV 8 bag filter 90-95% efficiency (Flanders). This is based on ASHRAE Standard 52.1, atmospheric dust spot test efficiency. The HVAC does not filter out of the facility.

**The design features:** AHU # 16 A and B are scheduled to supply a total of 44,200 CFM to the main animal facility. The university receives chilled water from a centralized location for the base power plant. Steam is also from a centralized location and provides 120psi high pressure steam. Temperature is regulated by zone. Hot water heat coil temperature ranges 120-180 depending on outside air tem for energy efficacy. They are equipped with glycol heat recovery coils and chilled water coils. The heat recovery coil is part of a run-around heat exchange system with the exhaust air through exhaust fans (EF) 16A and 16B. The units also each have a humidifier at the air handler. The units are mechanically designed to supply air at 55°F year-round. Exhaust fans for AHU #16A and 16B share a common suction header. In addition, VAV are in each a room to maintain constant volume by keeping the pressure at the same rate set by facilities department. Animal rooms

## Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

have a constant volume for pressure set point. Office work area are variable VAV set on demand. The two air handlers normally work independently of each other. Both AHU have an energy recovery unit.

**Room temp, hum and pressures:** The spaces served by AHUs 16A and 16B were designed to be balanced to a specific supply air volume and specific exhaust air volume. Each space has a reheat coil on the supply duct. Exhaust fans 16A and 16B exhaust air from the area served by AHUs 16A and 16B. They share a common suction header. After passing through the heat recovery coil, the air is routed vertically through the building where it is discharged in the fan enclosure on the roof of (b)(2). The ventilation system is capable of adjustments in dry-bulb temperatures of  $\pm 1^\circ\text{C}$  ( $\pm 2^\circ\text{F}$ ) and usually range from  $65^\circ\text{F}$  to  $85^\circ\text{F}$ . The set points for the currently housed species are as follows: Rodents –  $68-79^\circ\text{F}$ , Rabbits –  $61-72^\circ\text{F}$ , Swine –  $61-81^\circ\text{F}$ , and Ferrets –  $65-79^\circ\text{F}$ . Room ventilation rates are monitored annually and documented by Facilities. Professional air balancing is performed at least once every three years. This testing is inclusive of confirming air exchange rates, verifying minimum and maximum cfm with respect to design, and verifying correct directional air flow. The HVAC system includes re-heat coils that fail in the open position, however the system is equipped with a manual high-temperature cut-off system to prevent animal rooms from overheating.

**Redundancy:** There are no other HVAC backup systems for 16 A and B compare to the satellite animal holding rooms, however, a Consultant stated the current AHU# 16A and B is at an acceptable level of redundancy and no further action is recommended (b)(2); (b)(4)

back-up generators are present to supply power to the CAF. These generators will come on immediately in the event of a power failure. The generators are capable of running for 3 days before refueling is necessary. The generators are tested monthly. This configuration multiple plenum fans are in the same plane of the unit casing. The fan array tends to be more efficient and quieter than a single fan. There are no set points outside of the thermoneutral zone for any species. If the ability to provide heat or cooling to animal was compromised, portable heaters or fans are available. Additionally, extra bedding may be provided if temperatures are too low. The software is generally used for university HVAC control applications and it track back to 500 entries as set by facilities for temperature and humidity. Temperature, ventilation and critical air pressures are monitored by alarm devices. Room temperature, ventilation, and humidity is monitor daily by veterinary and husbandry staff, this includes weekends and holiday. Vet Technicians and husbandry twice a day during duty hours and twice on the weekend. After normal duty hours, there are float switch located in room (b)(2) that are monitored by USU security guards. When an alarm is goes off, the security staff notifies USU facility on call roster for the duty tech to evaluate the situation. The (b)(4) system is the university climate control system for temp, hum at the air handler and air flow for pressure.

### Air handling unit #23

**The source:** There are no HVAC backup systems for AHU 23 compare to the satellite animal holding rooms for system failure (total) backup. AHU-23 was replaced in 1997 and the manufacturer is (b)(4). The 100% outside air, constant volume unit is scheduled to supply 21,450 CFM to the (b)(2) area animal holding rooms.

## Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

**Treatment of air:** Ore-filters MERV 8 (95%) American Air filter Megapleat; Final filter MERV 8 bag filter 90-95% efficiency (Flanders). This is based on ASHRAE Standard 52.1, atmospheric dust spot test efficiency.

**The design features:** The unit has a humidifier. The unit is designed to supply air at 53°F year-round. Hot water heat coil temperature ranges 120-180 depending on outside air tem for energy efficacy. The university receives chill water from a centralized location building 16 for the base. Steam is also from a centralized location providing 120psi high pressure steam. Temperatures are regulated by zone. The ventilation system is capable of adjustments in dry-bulb temperatures of  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ) and usually range from 65°F to 85°F. They are equipped with glycol heat recovery coils and chilled water coils. The heat recovery coil is part of a run-around heat exchange system with the exhaust air through exhaust fans EF-16A and 16B. The units also each have a humidifier. The units also each have a dedicated humidifier. An exhaust fan for AHU-23 exhausts air from the area served by AHU-23. AHU# -23, has only one fan and motor. If either fails the system will be shut down. In addition, VAV are in each a room to maintain constant volume by keeping the pressure at the same rate set by facilities department. Office work area are variable VAV set on demand. The two air handlers (AHU 16A and B; and 23), normally work independently of each other. Both AHU have an energy recovery unit.

**Room temp, hum and pressures:** The spaces served by AHU-23 have constant volume boxes on the supply, but not on the exhaust. The constant volume boxes have reheat coils. Some of the zones have humidifiers. Room ventilation rates are monitored annually and documented by Facilities. Professional air balancing is performed at least once every three years. This testing is inclusive of confirming air exchange rates, verifying minimum and maximum cfm with respect to design, and verifying correct directional air flow. The HVAC system includes re-heat coils that fail in the open position, however the system is equipped with a manual high-temperature cut-off system to prevent animal rooms from overheating.

**Redundancy:** AHU-23 is not served by the university backup generator. There are no HVAC backup systems for AHU 23. There are no set points outside of the thermoneutral zone for any species. If the ability to provide heat or cooling to animal was compromised, portable heaters or fans are available. Additionally, extra bedding may be provided if temperatures are too low. (b)(2), (b)(4)

(b)(2) two back-up generators are present to supply power to the CAF. These generators will come on immediately in the event of a power failure. The generators are capable of running for 3 days before refueling is necessary. The generators are tested monthly. The software is generally used for university HVAC control applications and it track back to 500 entries as set by facilities for temperature and humidity. Temperature, ventilation and critical air pressures are monitored by alarm devices. Room temperature, ventilation, and humidity is monitor daily by veterinary and husbandry staff, this includes weekends and holiday. Vet Technicians and husbandry twice a day during duty hours and twice on the weekend. After normal duty hours, there are float switch located in room (b)(2) that are monitored by USU security guards. When an alarm is goes off, the security staff notifies USU facility on call roster for the duty tech to evaluated the situation. (b)(2) is an approved third party contractor the university blank purchase agreement. The arrangement three days a week per contract (b)(4) system, is the university climate control system for temp, hum at the air handler and air flow for pressure.

## Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

### Satellite animal holding rooms.

**The Source:** There are four satellite rooms that are located outside the central animal facility core. AHUs #24, 25, 26, 27, and 28 provide HVAC for animal rooms. (b)(2) Manufacture is (b)(4).

**Treatment of air:** Pre-filters MERV 8 (95%) American Air filter Megapleat; Final filter MERV 8 bag filter 90-95% efficiency (Flanders). This is based on ASHRAE Standard 52.1, atmospheric dust spot test efficiency.

**The design features:** The design features are chilled water/base supplied. Hot water heat coil temperature ranges 120-180 depending on outside air tem for energy efficacy. The university receives chill water from a centralized location for the base. Steam is also from a centralized location providing 120psi high pressure steam. Temperature are regulated by zone. The ventilation system is capable of adjustments in dry-bulb temperatures of  $\pm 1^{\circ}\text{C}$  ( $\pm 2^{\circ}\text{F}$ ) and usually range from 65°F to 85°F. Temperature is best regulated by having thermostatic control for each animal holding space and relative humidity control reheat for zonal. In addition, VAV are in each a room are constant volume by keeping the pressure at the same rate set by facilities department. Animal rooms constant volume for pressure set point. Office work area are variable VAV set on demand.

**Room temp, hum and pressures:** The spaces served by AHU-#24, 25, 26, 27, and 28 have constant volume boxes on the supply, but not on the exhaust. The constant volume boxes have reheat coils. Some of the zones have humidifiers. Room ventilation rates are monitored annually and documented by Facilities. Professional air balancing is performed at least once every three years. This testing is inclusive of confirming air exchange rates, verifying minimum and maximum cfm with respect to design, and verifying correct directional air flow. The HVAC system includes re-heat coils that fail in the open position, however the system is equipped with a manual high-temperature cut-off system to prevent animal rooms from overheating.

**Redundancy:** To reduce adverse consequences, the five AHU share a common duct system; if one fails, another will provide redundancy. There are no set points outside of the thermoneutral zone for any species. If the ability to provide heat or cooling to animal was compromised, portable heaters or fans are available. Additionally, extra bedding may be provided if temperatures are too low. (b)(2); (b)(4)

back-up generators are present to supply power to the CAF. These generators will come on immediately in the event of a power failure. The generators are capable of running for 3 days before refueling is necessary. The generators are tested monthly. The software is generally used for university HVAC control applications and it track back to 500 entries as set by facilities for temperature and humidity. Temperature, ventilation and critical air pressures are monitored by alarm devices. Room temperature, ventilation, and humidity is monitor daily by veterinary and husbandry staff, this includes weekends and holiday. Vet Technicians and husbandry twice a day during duty hours and twice on the weekend. After normal duty hours, there are float switch located in room (b)(2) that are monitored by USU security guards. When an alarm goes off, the security staff notifies USU facility on call roster for the duty tech to evaluated the situation. (b)(4) system, is the university climate control system for temp, hum at the air handler and air flow for pressure

## Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed within the 12 months preceding completion of this Program Description.* Air exchange rates may be important to maintain air quality in other areas; however, measurements may be left at the discretion of the institution. Information may be provided in another format, providing all requested data is included. **[Note: Please remove the examples provided in the Table below.]**

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
							(values to be measured)	
(b)(2)	OR C	69	Yes	65-85 F	Yes	positive	0.00	16-Oct-17
	OR D	69	Yes	65-85 F	Yes	positive	0.00	16-Oct-17
	OR B	69	Yes	65-85 F	Yes	neutral	0.00	16-Oct-17
	OR E	69	Yes	65-85 F	Yes	positive	0.00	16-Oct-17
	OR A	69	Yes	65-85 F	Yes	positive	0.00	16-Oct-17
	OR Prep room	69	Yes	65-85 F	Yes	positive	0.00	16-Oct-17
	X-ray room	69	Yes	65-85 F	Yes		0.00	16-Oct-17
	Storage	69	Yes	65-85 F	Yes	neutral	3.63	16-Oct-17

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
							(values to be measured)	
(b)(2)	Break down room	69	Yes	65-85 F	Yes	negative	4.83	16-Oct-17
	Instrument Room	69	Yes	65-85 F	Yes	negative	7.44	16-Oct-17
	Animal Receiving Room		No	N/A	No	positive	7.54	16-Oct-17
	Animal Receiving Room		No	N/A	No	positive	13.72	16-Oct-17
	Animal Receiving Room		No	N/A	No	positive	12.64	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	7.15	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	4.87	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	6.49	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	neutral	5.32	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	neutral	8.05	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	4.55	16-Oct-17
	Animal Holding gerbils	69	Yes	65-85 F	Yes	negative	8.89	16-Oct-17

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define Units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
							(values to be measured)	
							(settings to be verified)	
(b)(2)	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	10.07	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	12.45	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	11.50	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	9.34	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	8.98	16-Oct-17
	Animal Holding mouse	69	Yes	65-85 F	Yes	negative	9.53	16-Oct-17
	Animal Holding Rabbits	69	Yes	65-85 F	Yes	negative	9.42	16-Oct-17
	Necropsy Room	69	Yes	65-85 F	Yes	positive	7.71	16-Oct-17
	Procedure room	69	Yes	65-85 F	Yes	negative	11.20	16-Oct-17
	Procedure room	69	Yes	65-85 F	Yes	positive	0.00	16-Oct-17
	Procedure room	69	Yes	65-85 F	Yes	negative	10.88	16-Oct-17
	Procedure room	69	Yes	65-85 F	Yes	negative	10.91	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	10.59	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	11.70	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	11.39	16-Oct-17
	Procedure room	69	Yes	65-85 F	Yes		0.00	16-Oct-17



# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
							(values to be measured)	
(b)(2)	Animal Holding	69	Yes	65-85 F	Yes	positive	5.00	16-Oct-17
	Feed storage room	69	Yes	65-85 F	Yes	positive	7.07	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	13.12	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	11.02	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	10.60	16-Oct-17
	Feed storage room	69	Yes	65-85 F	Yes	positive	8.91	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	8.31	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	8.29	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	neutral	9.17	16-Oct-17
	Clean cage Storage	69	Yes	65-85 F	Yes	negative	18.27	16-Oct-17
	Clean cage Storage	69	Yes	65-85 F	Yes	negative	4.38	16-Oct-17
	Clean cage Storage	69	Yes	65-85 F	Yes	negative	4.99	16-Oct-17
	Cage wash area	69	Yes	65-85 F	Yes		0.00	16-Oct-17
	Barrier Autoclave area	69	Yes	65-85 F	Yes	positive	20.21	16-Oct-17
	Barrier procedure room	69	Yes	65-85 F	Yes	negative	3.90	16-Oct-17
Animal Holding	69	Yes	65-85 F	Yes	negative	12.17	16-Oct-17	



# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
							(values to be measured)	
(b)(2)	Animal Holding	69	Yes	65-85 F	Yes	negative	14.26	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	11.86	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	8.68	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	9.15	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	8.41	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	neutral	10.65	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	11.24	16-Oct-17
	Lab room	69	Yes	65-85 F	Yes	positive	3.53	16-Oct-17
	Procedure room	69	Yes	65-85 F	Yes	negative	5.31	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	19.33	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	13.43	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	3.86	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	12.78	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	8.09	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	9.95	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	20.18	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	15.23	16-Oct-17

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Room No.	Specific Use	Temperature Set-Point (define units)	Electronic / Emergency Monitoring of Temperatures (Y/N)	Alert/Alarm Temperature Ranges (if applicable; define units)	Humidity Control (Y/N)	Relative Pressure	Air Exchange Rate (per hour)	Date Verified / Measured
							(values to be measured)	
(b)(2)	Behavior Room	69	Yes	65-85 F	Yes	positive	14.65	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	13.84	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	13.73	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	13.78	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	16.94	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	12.00	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	positive	16.02	16-Oct-17
	Behavior Room	69	Yes	65-85 F	Yes	neutral	13.38	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	18.90	16-Oct-17
	Irradiator room	69	Yes	65-85 F	Yes	positive	8.14	16-Oct-17
	Animal Holding	72	Yes	65-85 F	Yes	negative	18.03	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	14.26	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	negative	15.39	16-Oct-17
	Animal Holding	69	Yes	65-85 F	Yes	positive	5.99	16-Oct-17

[Create additional rows by pressing TAB in the bottom-right box.]

**Copy and repeat the Description and Table for each location, including all satellite housing locations.**

## Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

- (1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number.  
Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
- (2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
- (3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
- (4) Indicate water type, e.g., fresh, brackish, or marine.
- (5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
- (6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
- (7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter).  
A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

### Part I

Part I							
Location (1)	Species (2)	System Design					
		Group / Individual (3)	Water Type (4)	Pre-treatment (5)	Circulation (6)	Filtration (7)	Disinfection (e.g., UV, ozone)
<u>N/A</u>							

Note: Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, etc.) should be available for review.

[Create additional rows by pressing TAB in the bottom-right box.]

## Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:

- (1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).
- (2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine

## Part II

[illegible]

**Note:** This information may be provided in another format, provided that all requested data is included.

[Create additional rows by pressing TAB in the bottom-right box.]

## Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field, and agricultural research studies.

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Rat	W -10.5" L -19" H-8"	2	Guide	Polycarbonate/Stainless Steel Static Microisolator
Mouse	W -7.5" L -11.5" H -5"	5	Guide	Manual Water Polycarbonate/Stainless Steel Static Microisolator
Mouse	W -8.5" L -12" H -6"	5	Guide	Manual Water Polycarbonate/Stainless Steel Individually ventilated cage
Rabbit	W -76" L -89" H -78"	3-4	Guide	Manual Water Metal Run with epoxy-coated concrete floor and half-wall
Ferret/Rabbit	W -34" L -28.5" H -25"	2/1	Guide	Stainless Steel Slatted Manual Water
Ferret	W -25" L -31.5" H -14.5"	2	Guide	Stainless Steel Slatted Manual Water

## Appendix 13: Primary Enclosures and Animal Space Provisions

Species	Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.)	Maximum Number Animals / Enclosure	Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other)	Enclosure Composition & Description**
Pig	W -76" L -89" H -78"	1-2	Guide	Metal run with epoxy-coated concrete floor and half-wall Plastic-coated slatted grates Automatic Water

\*For aquatic species, provide tank volume.

\*\*Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

## Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
<b>Micro-environment</b>				
Solid-bottom cages (static)	Tunnel washer	Twice a week	Alka-Det HW	Autoclave only barrier in (or barrier similar conditions, BSL-2 room out and PI requested cages.
Solid-bottom cages (IVC)	Tunnel washer	Twice a week	Alka-Det HW	Autoclave only barrier in (or barrier similar conditions, BSL-2 room out and PI requested cages.
Suspended wire-bottom or slotted floor cages	Tunnel washer	Twice a week	Alka-Det HW	Autoclave only barrier in (or barrier similar conditions, BSL-2 room out and PI requested cages.
Cage lids	Tunnel washer	Twice a week	Alka-Det HW	Autoclave only barrier in (or barrier similar conditions, BSL-2 room out and PI requested cages.
Filter tops	Tunnel washer	Twice a week	Alka-Det HW	Autoclave only barrier in (or barrier similar conditions, BSL-2 room out and PI requested cages.
Cage racks and shelves	Rack washer	Monthly	Alka-Det HW	

## Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

<b>Area</b>	<b>Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)</b>	<b>Washing/ Sanitizing Frequency</b>	<b>Chemical(s) Used*</b>	<b>Other Comments (e.g., autoclaved)</b>
Cage pans under suspended cages	High pressure foamer	Twice a week	Alka-Det HW Quatricide	Foamer first in the animal room and then run thru rack washer for BLS-2 agents
Play pens, floor pens, stalls, etc.	High pressure foamer		Quatricide	
Corrals for primates or outdoor paddocks for livestock	High pressure foamer	Daily for swine	Quatricide	
Aquatic, amphibian, and reptile tanks and enclosures	N/A	N/A	N/A	N/A
Feeders	Tunnel washer	Once a week for rodents, daily for all large animals; ferret, rabbits and swine	Alka-Det HW	Autoclave only barrier in (or barrier similar conditions, BSL-2 room out and PI requested cages.
Watering devices	Tunnel washer	Once a week for rodents, daily for all large animals; ferret, rabbits and swine.	Alka-Det HW	Autoclave only barrier in (or barrier similar conditions, BSL-2 room out and PI requested cages.
Exercise devices and manipulanda used in environmental enrichment programs, etc.		Once a week for rodents, weekly for all large animals: ferret, rabbits and swine.	Alka-Det HW	



## Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Transport cages	Rack washer	Limited large animal receiving, No more than 30 days, after 30 days will be rewashed	Alka-Det HW	
Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.)	Panepinto sling only	Limited large animal receiving, No more than 30 days, after 30 days will be rewashed	Quatricide	
Euthanasia chambers		After each use	MB-10 and Quatricide	
<b>Macro-Environment</b>				
<b>Animal Housing Rooms:</b>				
Floors	High pressure foamer hose	Monthly	Quatricide	
Walls	High pressure foamer hose	Monthly	Quatricide	
Ceilings	High pressure foamer hose	Monthly	Quatricide	
Ducts/Pipes	Hand wiped and sprayed	Monthly	Quatricide	
Fixtures	Hand wiped and sprayed	Monthly	Quatricide	

## Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
<b>Corridors:</b>				
Floors	High-pressure sprayers	Daily/weekly	Quatricide	Depends on the traffic area
Walls	High-pressure sprayers	Monthly	Quatricide	
Ceilings	High-pressure sprayers	Monthly	Quatricide	
Ducts/Pipes	High-pressure sprayers	Monthly	Quatricide	
Fixtures	High-pressure sprayers	Monthly	Quatricide	
<b>Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:</b>				
Floors	Sweep/Wet mop	weekly	Quatricide	
Walls	Hand washing	weekly	Quatricide	
Ceilings	N/A			
Ducts/Pipes	N/A			
Fixtures	Hand washing		Quatricide	
<b>Implements (note whether or not shared):</b>				
Mops	Mechanical washer Not shared in animal holding rooms, shared only in common areas	daily-weekly	Quatricide/ Alka-Det HW	
Mop buckets	Mechanical washer Not shared in animal holding rooms, shared only in common areas	Monthly	Quatricide/ Alka-Det HW	

## Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Area	Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.)	Washing/ Sanitizing Frequency	Chemical(s) Used*	Other Comments (e.g., autoclaved)
Aquaria nets	N/A	N/A		
Other	N/A	N/A		
<b>Other:</b>				
Vehicle(s)	Hose/disinfectant	Before and after use	MB-10	
Other transport equipment (list)		Before and after use. Drapes will be sent out with the laundry	Before and after use	

\*Please provide chemical, not trade name.

## Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, etc.). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

[Note: Please remove the examples provided in the Table below.]

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
Bldg C	(b)(2)	Rack washer 1	Emergency "off" button on the side of each door with a red sign; labeled push here to exit inside of each door, de-energizing cord on both sides, instructional signage pull cable to stop Each side has a door window and a light inside. Electrical panel shut off.	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly.
Bldg C		Rack washer 2	Emergency "off" button on the side of each door with a red sign; labeled push here to exit inside of each door, de-energizing cord on both sides, instructional signage pull cable to stop Each side has a door window and a light inside. Electrical panel shut off.	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly
Bldg C		Tunnel washer	Emergency "off" button; instructional signage. Signs throw out the machine; danger hot, do not open when machine is operating, high voltage, pinch point hazards, danger hot and hot. Has photo eye sensors for motion	Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly
Bldg C		Dirty Bedding chain removal system	Emergency "off" button and signage, touch screen notify when dumpster is gone. Electrical panel shut off. Arc flashing shock hazards loose screws and parts	

## Appendix 15: Facilities and Equipment for Sanitizing Materials

Building	Room No.	Equipment Type	Safety Feature(s)	Methods of Monitoring Effectiveness
Bldg C	(b)(2)	Bedding dispensing unit	Emergency "off" button with signage. Do not operate without guard in place. Photo-eye sensor	
Bldg C		Autoclave	None	Biological Indicators and Bowie-Dick
Bldg C		Autoclave	None	Biological Indicators and Bowie-Dick
Bldg C		Autoclave	Emergency "off" button; lock-out key	Biological Indicators and Bowie-Dick
Bldg C		Autoclave	None	Biological Indicators and Bowie-Dick
Bldg C		Autoclave	Emergency "off" button; lock-out key	Biological Indicators and Bowie-Dick
Bldg C		Bedding dispensing unit	Emergency "off" button	N/A

[Create additional rows by pressing TAB in the bottom-right box.]

## Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

**Location:** USUHS Central Animal Facility

**[Note: Please remove the examples provided in the Table below.]**

Room Type <sup>(a)</sup>	Light Intensity Range	Lighting Fixture Construction Features <sup>(b)</sup>	Photo-period (hrs) <sup>(c)</sup>	Photoperiod and Lighting Control	Override Mechanisms (if applicable)
Rodent	107-385	Surface mounted; some with red lighting	12:12	Automatic via wall-mounted timer box	Mechanical on/off switches
Ferret	114-381	Surface mounted	16:8 and 12:12	Automatic via wall-mounted timer box	Mechanical on/off switches
Rabbit	214	Surface mounted	12:12	Automatic via wall-mounted timer box	Mechanical on/off switches
Swine	115	Surface mounted	12:12	Automatic via wall-mounted timer box	Mechanical on/off switches
Opossum	368	Surface mounted	14:10	Automatic via wall-mounted timer box	Mechanical on/off switches
Surgery Rooms	148-990	Surface mounted	N/A	N/A	N/A
Storage	216-300	Surface mounted	N/A	N/A	N/A
Procedure rooms	119-543	Surface Mounted	N/A	Automatic via wall-mounted timer box	Mechanical on/off switches

[Create additional rows by pressing TAB in the bottom-right box.]

<sup>(a)</sup> A list of each room is not needed; group or cluster rooms by species or function

<sup>(b)</sup> Include such features as water resistance, red lighting, etc.

<sup>(c)</sup> Note if light cycle inverted/reversed.

**Repeat Location and Table as necessary for each location, including satellite housing locations.**

## Appendix 17: Satellite Housing Facilities

Note: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that each of these must also be included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (Appendix 11) and Lighting Systems Summary (Appendix 16).

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft <sup>2</sup> or m <sup>2</sup> ) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes
Bldg B	(b)(2)	(b)(6)	Mouse	207 square feet	Indefinite	Infectious diseases study/ protocol depended	Smooth, monolithic, seamless, epoxy aggregate floor system with integral coving. Walls are Concrete Masonry Unit construction with epoxy paint coating. Ceilings in corridors, animal, procedure, and cage wash areas are made of epoxy-coated concrete or moisture resistant plasterboard (b)(2) cage wash).
Bldg B			Mouse	200 square feet	6-8 Weeks	Unapproved source quarantine	Smooth, monolithic, seamless, epoxy aggregate floor system with integral coving. Walls are Concrete Masonry Unit

## Appendix 17: Satellite Housing Facilities

Building	Room(s)	Person Responsible	Species Used	Approximate Area (ft <sup>2</sup> or m <sup>2</sup> ) Devoted to Housing	Maximum Period of Stay	Purpose / Rationale / Justification	Construction Features and Finishes
	(b)(2)	(b)(6)					construction with epoxy paint coating. Ceilings in corridors, animal, procedure, and cage wash areas are made of epoxy-coated concrete or moisture resistant plasterboard (b)(2) (cage wash).
Bldg B			Opossum	200 square feet	Indefinite	Unknown health status, usually species	Smooth, monolithic, seamless, epoxy aggregate floor system with integral coving. Walls are Concrete Masonry Unit construction with epoxy paint coating. Ceilings in corridors, animal, procedure, and cage wash areas are made of epoxy-coated concrete or moisture resistant plasterboard (b)(2) (cage wash).
Bldg C			Gerbils	212 square feet	Indefinite	Tropical rat mites	Smooth, monolithic, seamless, epoxy aggregate floor system with integral coving. Walls are Concrete Masonry Unit



## Appendix 17: Satellite Housing Facilities

[illegible]

[Create additional rows by pressing TAB in the bottom-right box.]